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**RAINDroP Randomised IroN Deficency anaemia management Pilot**

**Case Report Form**

**SPONSOR ID:** 3.023.18

**IRSCTN NO:** 98371961

**REC ID:** 18/NS/0064

**SITE:** Newcastle

**IRAS ID:** 233417

**CHIEF INVESTIGATOR:**
Professor Phyo Myint
Professor of Old Age Medicine
Institute of Applied Health Sciences
University of Aberdeen
Aberdeen Royal Infirmary
Aberdeen AB25 2ZD

**PRINCIPAL INVESTIGATOR:**
Professor Miles Witham
Clinical Ageing Research Unit (CARU)
Biomedical Research Building Campus for Ageing and Vitality
Newcastle University
NE4 5PL

**Randomised:** **Yes** ☐ No ☐

**Randomisation date:** D D – M M – Y Y Y Y

*To be signed once participant has completed study*.

I have reviewed this CRF and confirm that, to the best of my knowledge, it accurately reflects the study information obtained for this participant.
All entries were made either by myself or by a person under my supervision who has signed the Delegation and Signature Log.

**PRINCIPAL INVESTIGATOR SIGNATURE:** _____

**DATE OF SIGNATURE:** D D – M M – Y Y Y Y

**Guidelines for Case Report Form (CRF) Completion:**

All clinical data collected during the study must be documented in this CRF or data capture forms.
Any person entering data into the CRF should be delegated this role by the Principal Investigator and recorded on the Delegation Log.
Please use a black ball-point pen for filling in the case report form.

Incorrect entries should be deleted with a single line. The original entry must be kept legible. All changes and/or corrections made to the case report form must be initialled and dated by the person making the change.

Please answer all questions and write clearly.

Identification of participants throughout the study is by participant ID only.

Please enter only one digit in one box. Data should be entered at the right hand margin. If not enough digits are available to fill all fields, please prefix the number by recording "0". E.g. 19 would be entered as | 0 | 1 | 9 |

Please enter complete dates wherever possible, format: DD-MM-YYYY
If day or month of a date should be unknown, please enter "NK" in the respective fields. e.g.: NK-05-2012

If a result is zero, please enter "0".

If a page has not been used, please enter the participant ID and initials and cross out the page.

Comments should be as short as possible. **Please do not enter comments outside the predefined areas**.

Abbreviations should not be used.
**Front Page**

- If the participant is a screen fail complete a *Completion of Trial Form*.
- The Participant ID is allocated by the HIC Recruitment Tracker System (Cohort ID); and used to identify each participant throughout the study.
- Complete participant initials, if participant only has 2 initials insert dash in middle e.g. A-B
- Once a participant has completed the study, either screen fail, withdrawal, death or completion, PI should sign off front page.

**Screening Visit / Medication:**

Use the following frequency Code:

Once per Day = OD  Twice per Day = BD  Three times per day = TI

| Participant ID | | | | | |
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## Visit 1 (Screening and Baseline visit)

Date of visit: D D – M M – Y Y Y Y

## Informed Consent

Has the participant freely given written informed consent? Yes ☐ No ☐

Date of Consent: D D – M M – Y Y Y Y

## Demographic Details

Date of birth: D D – M M – Y Y Y Y

Gender: ☐ Male ☐ Female

## Medication

**Oral Iron:**

| | *tick which applies* | Dose | Unit | Frequency |
|---|---|---|---|---|
| Ferrous sulphate | | | | |
| Ferrous fumarate | | | | |
| Ferrous gluconate | | | | |
| Other (specify)…….. | | | | |

**Concomitant Medication:**

Record all current medication (other than oral iron recorded above) in Concomitant Medication Form

**Bloods test results**

- Blood results obtained from medical record / laboratory report:
- Haemoglobin and ferritin results prior to starting oral iron are required to determine eligibility:
    - **Where results are not available to participant is ineligible**.
- Haemoglobin and ferritin results after a minimum of 8 weeks oral iron therapy.
    - Where Haemoglobin results after a minimum of 8 weeks oral iron therapy are not available participant is ineligible
    - Where ferritin results after a minimum of 8 weeks oral iron therapy are not available participant is eligible but ferritin must be taken at baseline visit for final eligibility.

If available, and within 12 months of Visit 1, creatinine and eGFR will be used to assess eligibility; otherwise baseline sample results are required for eligibility assessment.

- Where creatinine and eGRF are not available within 12 months of visit one (baseline / screening) and samples are not taken at this visit then the participant is ineligible

Please enter only one digit in one box. Data should be entered at the right hand margin. If not enough digits are available to fill all fields, please prefix the number by recording "0".
E.g. 19 would be entered as

| | | |
|---|---|---|
| 0 | 1 | 9 |

Refer to OpenClinica date entry notes

Ferritin results reported with a decimal place will be rounded:

- Where 0.4 and below round down e.g. 28.4 record as 28
- Where 0.5 and above round up e.g. 28.5 record as 29

Where ferritin result, after commencing oral iron therapy, is not available leave result and date field blank.
If the result is not available then the baseline ferritin result is required for eligibility assessment.

C-reactive protein results reported with a less than symbol (<) will be recorded as the whole number below e.g. <04 record as 03.

For eGFR if the result is greater than (>) please enter "GT" in the first box.

E.g. >60 would be entered as

| | | |
|---|---|---|
| GT | 6 | 0 |

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| Blood test results from clinical record | |
|---|---|
| Haemoglobin prior to starting iron | g/L |
| Ferritin prior to starting iron | ug/L |
| Date of starting oral iron | D D – M M – Y Y Y Y |
| Most recent Haemoglobin after a minimum of 8 weeks oral iron | g/L |
| Date of Haemoglobin after a minimum of 8 weeks oral iron | D D – M M – Y Y Y Y |
| Most recent ferritin after minimum 8 weeks oral iron | ug/L |
| Date of ferritin after minimum of 8 weeks oral iron | D D – M M – Y Y Y Y |
| Creatinine (within 12 months) | umol/L |
| Date of Creatinine: | D D – M M – Y Y Y Y |
| Tick if not available: | ☐ |
| eGFR (within 12 months) | ml/min/1.73m2 |
| Date of eGFR | D D – M M – Y Y Y Y |
| Tick if not available: | ☐ |

**Inclusion Criteria**

- Ensure that participants are aged 65 or over on the date of Visit 1, to comply with inclusion criteria 3.
- Medical notes will be reviewed to assess eligibility.

| Participant ID | | | | | |
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## Eligibility

**INCLUSION Criteria**

| **The following criteria MUST be answered YES for participant to be included in the trial.** | | **YES** | **NO** |
|---|---|---|---|
| **1.** | Provision of written informed consent | | |
| **2.** | Community dwelling (i.e. not in hospital) | | |
| **3.** | Age 65 years or over | | |
| **4.** | Haemoglobin greater than or equal to (≥) 85g/L **AND** haemoglobin less than or equal to ( ≤) 110g/L prior to commencing oral iron | | |
| **5.** | Ferritin less than (<)100ug/L prior to commencing oral iron | | |
| **6.** | Currently taking oral iron at any dose with a minimum of 8 weeks therapy | | |
| **7.** | Does the patient meet one of criteria below? *Please indicate which*<br><br>☐ a. Insufficient response to oral iron therapy<br>(sufficient response defined as improvement in Hb of 20g/L after a minimum of 8 weeks of oral iron therapy or above lower limit of normal Hb level for sex)<br><br>☐ b. Oral iron therapy provided an initial sufficient response however Hb has now fallen below lower limit of normal for sex (sufficient response defined as improvement in Hb of 20g/L after a minimum of 8 weeks of oral iron therapy or above lower limit of normal Hb level for sex) | | |
| **8.** | Relevant investigations (including upper and lower GI endoscopies) either already conducted, offered but declined by the patient, or deemed not appropriate by the treating clinician. | | |

***IF NO TO ANY OF THE ABOVE INCLUSION CRITERIA, THE PARTICIPANT IS INELIGIBLE FOR THE STUDY>SCREEN FAIL>COMPLETE "COMPLETION OF TRIAL FORM"**

**Exclusion Criteria**

- Oral anticoagulants (antiplatelet agents are permitted, e.g. aspirin, dipyridamole, clopidogrel) see link below for further information: https://bnf.nice.org.uk/treatment-summary/antiplatelet-drugs.html

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| **Eligibility cont.** | | | |
|---|---|---|---|
| **EXCLUSION Criteria** | | | |
| **The following criteria MUST be answered NO for participant to be included in the trial.** | | **YES** | **NO** |
| **1.** | Active GI cancers | | |
| **2.** | Active (unhealed) peptic ulcer disease | | |
| **3.** | Bleeding disorders | | |
| **4.** | Taking oral anticoagulants (antiplatelet agents are permitted) | | |
| **5.** | Weight loss of more than (>)5kg in last 3 months (as a possible maker of occult cancer) | | |
| **6.** | Estimated GFR of less than (<)30ml/min/1.73m$^2$ by CKD-EPI equation | | |
| **7.** | Symptomatic chronic heart failure (NYHA III to IV)<br>Note: asymptomatic left ventricular systolic or diastolic dysfunction is not classed as heart failure; the use of heart failure medications are permitted | | |
| **8.** | Terminal illness with life expectancy less than 3 months as deemed by the local investigator | | |
| **9.** | Severe cognitive impairment precluding written informed consent | | |
| **10.** | Unable to mobilise without human assistance (walking aids are allowed) | | |
| **11.** | Previous reaction to intravenous iron | | |
| **12.** | Participating in another clinical trial (other than observational trials and registries) concurrently or within 30 days prior to screening form entry into this study. | | |
| ***IF YES TO ANY OF THE ABOVE INCLUSION CRITERIA, THE PARTICIPANT IS INELIGIBLE FOR THE STUDY>SCREEN FAIL>COMPLETE "COMPLETION OF TRIAL FORM"** | | | |

**Home Circumstances and Walking Aids**

- Participant will be asked to describe their home circumstances (record all that apply e.g. if living alone and in sheltered housing record both) and use of care services, and where applicable number of hours per week.
- Walking aids used outside the home, record those used at Visit 1 e.g. if zimmer and stick are brought to the visit record both.

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| Home circumstances | | | | | | | | | | |
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| **Please record all which are applicable** | | | | | | | | | | |
| Living alone | Yes | | No | | | | | | | |
| Living with family | Yes | | No | | | | | | | |
| Sheltered housing | Yes | | No | | | | | | | |
| Residential/nursing home | Yes | | No | | | | | | | |
| | | | | | | | | | | |
| Using care services | Yes | | No | | | | | | | |
| If using care services, how many hours per week | | | | | | | | | hours | |

| Walking Aids | | | | | |
|---|---|---|---|---|---|
| **Please record which are applicable today** | | | | | |
| Nil (unaided) | Yes | | No | | |
| Stick (s) | Yes | | No | | |
| Tri-wheeler | Yes | | No | | |
| Zimmer frame | Yes | | No | | |
| Other | Yes | | No | | |
| If other please specify …… | | | | | |

**Height, Weight & BMI**

- Height and weight will be measured using local equipment and protocol; flat shoes and indoor clothing (no coats / heavy jackets) can be worn.

- BMI will be calculated using the NHS BMI calculator.
    - www.nhs.uk/Tools/Pages/Healthyweightcalculator.aspx

**Blood Samples**

- Where samples are not taken and were available at screening please complete deviation log.
- NOTE: if ferritin, creatinine and eGRF are required for eligibility and not bloods are taken, the participant is ineligible.

| Participant ID | | | | | |
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## Height and Weight

Height: [ ] . [ ][ ] m

Weight: [ ][ ][ ] . [ ] Kg

BMI [ ][ ] . [ ]

## Blood Samples

| | | | | |
|---|---|---|---|---|
| Haemoglobin sample taken? | Yes | [ ] | No | [ ] |
| Ferritin sample taken? | Yes | [ ] | No | [ ] |
| C-reactive protein, creatinine & eGFR sample taken? | Yes | [ ] | No | [ ] |

**Past Medical History**

The Medical History section should be completed as fully as possible and should be as diagnosed by a doctor.

- Relevant medical history will be recorded in the CRF, using a tick for yes or no; tick against each listed condition; tick yes where the condition has been diagnosed.
- Date of diagnosis is not required.
- Additional details are not required, i.e. do not annotate CRF to provide extra information.
- Only where other medical conditions are reported (i.e. not listed on CRF page) is a written response required. The "other medical history" should include:
    - Currently active medical conditions
    - Medical conditions which the participant is receiving concomitant medications
    - Past medical conditions which impact on the participants' Activities of Daily Living or ability to complete the trial assessments.
    - Abbreviations should be avoided.

**Medical History CRF page definitions**:

TIA: Transient Ischaemic Attack

Diabetes Mellitus = Type 1 or Type 2

Chronic Kidney Disease Stage 3a eGFR = 45-59mlL/min (NICE CG182)

Fragility fractures: Fractures that result from low-level (or 'low energy') trauma that is caused by mechanical forces that would not ordinarily result in a fracture. The World Health Organization (WHO) has quantified this as forces equivalent to a fall from a standing height or less.

Ref: February 2012, NICE, Osteoporosis: assessing the risk of fragility fracture, NICE guideline, Draft for consultation.

BCC: Basal Cell Carcinoma

SCC: Squamous Cell Carcinoma

COPD: Chronic Obstructive Pulmonary Disease

Liver disease: yes if either (or both) cirrhosis or chronic hepatitis

Other: see above

| Participant ID | | | | | |
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## Past Medical History

| | Yes | No |
|---|---|---|
| 1. Myocardial infarction | | |
| 2. Chronic heart failure | | |
| 3. Peripheral vascular disease | | |
| 4. Stroke or TIA | | |
| 5. Hypertension | | |
| 6. Diabetes mellitus | | |
| 7. Chronic kidney disease (stage 3a or worse) | | |
| 8. Parkinsonism | | |
| 9. Previous fragility fracture (any site) | | |
| 10. Cancer diagnosis within last 5 years (excl. BCC or SCC) | | |
| 11. Osteoarthritis | | |
| 12. Rheumatoid arthritis | | |
| 13. COPD | | |
| 14. Liver disease (cirrhosis or chronic hepatitis) | | |
| 15. Other connective tissue disease | | |
| 16. Dementia | | |
| 17. Peptic ulcer disease (within last 5 year) | | |
| 18. Oesophagitis (confirmed on endoscopy within last 10 yrs) | | |
| 19. Other (Specify Diagnosis) | | |
| | | |
| | | |

**SHORT PHYSICAL PERFORMANCE BATTERY PROTOCOL**

**Requirements:**
Stopwatch
Chair
3 metre walking course

**Perform tests in order presented.**
**Instructions to the participant are shown in bold italic and should be given as they are written.**
Where a test is not completed provide number of seconds and reason for failure/not attempted then proceed to next test e.g. if gait speed not completed go to chair stand (as instructed in CRF).

**1. BALANCE TESTS**
The participant must be able to stand unassisted without the use of a cane or walker. You may help the participant to get up.

***Now let's begin the evaluation. I would now like you to try to move your body in different movements. I will first describe and show each movement to you. Then I'd like you to try to do it. If you cannot do a particular movement, or if you feel it would be unsafe to try to do it, tell me and we'll move on to the next one. Let me emphasize that I do not want you to try to do any exercise that you feel might be unsafe.***
***Do you have any questions before we begin?***

**a) Side-by-Side Stand**

1. ***Now I will show you the first movement***.
2. (Demonstrate) ***I want you to try to stand with your feet together, side-by-side, for about 10 seconds.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the side-by-side position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

**b) Semi-Tandem Stand**

1. ***Now I will show you the second movement***.
2. (Demonstrate) ***Now I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the semi-tandem position
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

## Short Physical Performance Battery (SPPB)

***All of the tests should be performed in the same order as they are presented in this CRF. Instructions to the participants are shown in bold italic and should be given exactly as they are written in this script. Please refer to instructions on facing page.***

**1.Balance Tests** ***please tick only one per test; leave other fields blank***

**a) Side-by-side Stand**

Held for 10 sec ☐ **→Go to Semi-tandem Stand (below)**

Not held for 10 sec ☐ Number of seconds if less than 10 sec: ☐ . ☐

Not attempted ☐

***If participant did not attempt test or failed to hold for 10 sec, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

***→Go to Gait Speed Test (next page)***

**b) Semi-tandem Stand**

Held for 10 sec ☐ **→Go to Tandem Stand (following page)**

Not Held for 10 sec ☐ Number of seconds if less than 10 sec: ☐ . ☐

Not attempted ☐

***If participant did not attempt test or failed to complete, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

***→Go to Gait Speed Test (next page)***

**c) Tandem Stand**

1. ***Now I will show you the third movement***.
2. (Demonstrate) ***Now I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the tandem position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

**2. GAIT SPEED TEST**

**Mark out a 3 metre walking course.**
***Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.***

**a) First Gait Speed Test**
1. ***This is our 3 metre walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.***
2. Demonstrate the walk for the participant.
3. ***Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?***
4. Have the participant stand with both feet touching the starting line.
5. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
6. Press the start/stop button to start the stopwatch as the participant begins walking.
7. Walk behind and to the side of the participant.
8. Stop timing when one of the participant's feet is completely across the end line.

**b) Second Gait Speed Test**
1. ***Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.***
2. Have the participant stand with both feet touching the starting line.
3. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
4. Press the start/stop button to start the stopwatch as the participant begins walking.
5. Walk behind and to the side of the participant.
6. Stop timing when one of the participant's feet is completely across the end line.

## SPPB continued

c) **Tandem Stand**

Held for <3.00 sec ☐ ***→Go to Gait Speed Test (below)***

Held for 3.00 to 9.99 sec ☐ ***→Go to Gait Speed Test (below)***

Held for 10 sec ☐ ***→Go to Gait Speed Test (below)***

Not Attempted ☐

***If participant did not attempt test, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

***→Go to Gait speed test (below)***

**2. Gait Speed Test (3 metre course)**

**a) Gait Speed Test 1**

Not attempted/not able ☐

***If participant did not attempt test or failed to complete, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

**→Go to Chair Stand (next page)**

Gait Speed time 1 ☐☐ . ☐ seconds

***→Repeat Gait Speed Test***

**b) Gait Speed Test 2**

Not attempted/not able ☐ **→Go to Chair Stand (next page)**

***If participant did not attempt test or failed to complete, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

Gait Speed time 2 for 3 m ☐☐ . ☐ Seconds **→Go to Chair Stand (next page)**

**3. CHAIR STAND TEST**

**Single Chair Stand**

1. ***Let's do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms?***
2. ***The next test measures the strength in your legs.***
3. (Demonstrate and explain the procedure.) ***First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest.***
4. ***Please stand up keeping your arms folded across your chest.*** (Record result).
5. If participant cannot rise without using arms, say ***"Okay, try to stand up using your arms."*** This is the end of their test. Record result.

**Repeated Chair Stands**

1. ***Do you think it would be safe for you to try to stand up from a chair five times without using your arms?***
2. (Demonstrate and explain the procedure): ***Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I'll be timing you with a stopwatch.***
3. When the participant is properly seated, say: ***"Ready? Stand"*** and begin timing.
4. Count out loud as the participant arises each time, up to five times.
5. Stop if participant becomes tired or short of breath during repeated chair stands.
6. Stop the stopwatch when he/she has straightened up completely for the fifth time.
7. Also stop:

• If participant uses his/her arms
• After 1 minute, if participant has not completed rises
• At your discretion, if concerned for participant's safety

8. If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking ***"Can you continue?"***
9. If participant says "Yes," continue timing. If participant says "No," stop and reset the stopwatch.

| Participant ID | | | | | |
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## SPPB continued

**Single Chair Stand Test**

**Results:**

Participant stood without using arms ☐ **→Go to Repeated Chair Stand Test**

Participant used arms to stand ☐ **→End Test**

Test not completed ☐ **→End Test**

***If participant did not attempt test or failed to complete, please select reason from list below:*** ☐

If other (6) please specify……

1.Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

**Repeated Chair Stand Test**

Five stands completed Yes ☐ No ☐ **→End Test**

If five stands done successfully record the time in seconds

Time to complete five stands: ☐☐.☐ seconds

***If participant did not attempt test or failed to complete, please select reason from list below*** ☐

If other (6) please specify……

1.Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

**Six-minute walk test INSTRUCTIONS**

**Instructions to the participant are shown in bold italic and should be given as they are written.**
With the participant sitting explain ***'We are interested in how far you can comfortably walk in 6 minutes, at you usual speed and using your walking aid as needed (if relevant). I will ask you to walk up and down the corridor. You can slow down if you need. If you need to stop we will end the test. I will record each time you cross the starting line. You should turn around the cones and continue back the other way without hesitation. Now I'm going to show you'.***
Demonstrate by walking one lap yourself. Turn around the cone briskly.
Ask participant to stand up next to the starting line. ***'Are you ready? The aim is to walk AS FAR AS POSSIBLE for 6 minutes, but don't jog or run. Please walk up and down the corridor, around the cones for the next 6 minutes. Walk at your usual speed and try to walk as far as possible. Use your walking aid as needed (if relevant). If you need to stop please tell me. I will walk behind you so as not to affect your walking speed. Please start when you are ready'.***

**Equipment needed**
1. A 30 metre, pre-measured flat walking area with interval markings every three metres.
2. Cones or brightly coloured tape to mark boundaries of the course
3. Watch or timer to time 6 minutes
4. Chair available if participant needs to stop test
5. Temporary marker to mark and measuring tape measure finish point
6. A source of oxygen
7. BP machine or Sphygmomanometer & Stethoscope
8. Telephone
9. Automated electronic defibrillator

**Absolute contraindications for the 6MWT include the following:**
Unstable angina during the previous month and myocardial infarction during the previous month.

**Relative contraindications include**
A resting heart rate of more than 120,
A systolic blood pressure of more than 180 mm Hg, and a diastolic blood pressure of more than 100 mm Hg.

**Participant preparation**
1. Comfortable clothing and appropriate shoes for walking should be worn.
2. Patients should use their usual walking aids during the test (cane, walker, etc.).
3. The patient's usual medical regimen should be continued.
4. A light meal is acceptable before early morning or early afternoon tests.
5. Patients should not have exercised vigorously within 2 hours of beginning the test.

**Reasons for immediately stopping a 6MWT**
(1) Chest pain, (2) intolerable dyspnoea, (3) leg cramps, (4) staggering, (5) diaphoresis, and (6) pale or ashen appearance.
Testing should be performed in a location where a rapid, appropriate response to an emergency is possible.
The appropriate location of a crash cart/trolley should be determined by the physician supervising the facility.
Supplies that must be available include oxygen, sublingual nitro-glycerine, aspirin, and metered dose inhaler or nebulizer. A telephone or other means should be in place to enable a call for help. The technician should be certified in cardiopulmonary resuscitation with a minimum of Basic Life Support. Advanced cardiac life support certification is desirable. Training, experience, and certification in related health care fields (registered nurse, registered respiratory therapist, certified pulmonary function technician, etc.) are also desirable. A certified individual should be readily available to respond if needed. Physicians are not required to be present during all tests. The physician ordering the test or a supervising laboratory physician may decide whether physician attendance at a specific test is required. If a patient is on chronic oxygen therapy, oxygen should be given at their standard rate or as directed by a physician or a protocol.

**Questionnaires** – this list is a checklist only, and not entered into OpenClinica.

| Participant ID | | | | | |
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## Six minute walk test

Test completed without stops? Yes ☐ No ☐

Distance walked ☐☐☐ metres

If less than six minutes walked, please record time ☐ : ☐☐ minutes

If "No" please select reason from list below: ☐

1. Chest pain
2. Intolerable dyspnoea
3. Leg cramps
4. Staggering
5. Diaphoresis
6. Pale or ashen appearance
7. Participant refused

## Questionnaires

| Please indicate completion | | | | | |
|---|---|---|---|---|---|
| Oral Iron use scale | Yes | | No | | |
| Fatigue Severity Scale | Yes | | No | | |
| Patient Reported Anaemia Symptoms | Yes | | No | | |
| EQ-5D-5L™ | Yes | | No | | |
| 15D© | Yes | | No | | |
| Nottingham EADL© | Yes | | No | | |
| Health & Care Use | Yes | | No | | |

**Blood sample results**

Please enter only one digit in each box. Data should be entered at the right hand margin. If not enough digits are available to fill all fields, please prefix the number by recording "0".

E.g. 19 would be entered as

| | | |
|---|---|---|
| 0 | 1 | 9 |

Refer to OpenClinica data entry notes.

Ferritin results reported with a decimal place will be rounded:

- Where 0.4 and below round down e.g. 28.4 record as 28
- Where 0.5 and above round up e.g. 28.5 record as 29

Where ferritin result 8 weeks after commencing oral iron therapy, is not available, the baseline sample result is required for eligibility assessment:

- If (baseline) ferritin is not taken then the participant is not eligible.

If ferritin is not required at Visit 1 for eligibility (i.e. ferritin after minimum of 8 weeks oral iron treatment is available) and is not done:

- leave results field blank.

C-reactive protein results reported with a less than symbol (<) will be recorded as the whole number below e.g. <04 record as 03.

For eGFR if the result is greater than (>) please enter "GT" in the first box.

E.g. >60 would be entered as

| | | |
|---|---|---|
| GT | 6 | 0 |

| Participant ID | | | | | |
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| Initials | | |
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## Baseline Blood sample results

| | | |
|---|---|---|
| Haemoglobin | | g/L |
| Ferritin | | ug/L |
| C-reactive protein | | mg/L |
| Creatinine | | umol/L |
| eGFR | | ml/min/1.73m2 |

## Participant Eligibility/Investigator Sign Off

Are ALL inclusion/exclusion criterion met? Yes ☐

Is the participant eligible to take part in the clinical trial? Yes ☐

Investigator's Name: _____

Investigator's Signature: _____

Date of signature: D D – M M – Y Y Y Y

**Visit 2 – Telephone Visit Instructions**

To be carried out within 4 days of randomisation.

Telephone participant.

Confirm they are happy to continue in the study.

Ask about any AEs since Screening/Baseline visit, record in AE log if applicable.

Advise participant of randomisation allocation, and arrange appointment for IV Iron infusion if required.

**Visit 3 – Iron IV visit**

Only those participants randomised to receive IV iron will have a visit 3. This will not be recorded in the CRF as this would unblind the study. Details of the IV iron preparation will be recorded by the unblinded research nurse on the iron treatment Excel sheet, held separately from the CRF

## Visit 2 (Telephone visit)

Date of visit D D – M M – Y Y Y Y

## Consent

Is the participant happy to continue in the trial? Yes ☐ No ☐

*If "No" please complete withdrawal form*

## Adverse Events (AEs)

Experienced any AEs since screening/baseline visit? Yes ☐ No ☐

*If "Yes" please complete AE log*

**Visit 3 (Iron Infusion visit)**

Details if applicable should be recorded in the separate iron treatment Excel spreadsheet.

**Visit 4 – Follow up**

The physical assessments must be carried out before recording any Adverse Events (AEs) and concomitant medications.

| Participant ID | | | | | |
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## Visit 4 (Final visit)

Date of visit D D – M M – Y Y Y Y

## Consent

Is the participant happy to continue in the trial? Yes ☐ No ☐

*If "No" please complete withdrawal form*

**Visit 4 Follow up Outcome Assessment Visit**

## Please carry out assessments prior to recording any AEs/Con meds

**SHORT PHYSICAL PERFORMANCE BATTERY PROTOCOL**

**Requirements:**

Stopwatch
Chair
3 metre walking course

**Perform tests in order presented.**

**Instructions to the participant are shown in bold italic and should be given as they are written.**

Where a test is not completed provide number of seconds and reason for failure/not attempted then proceed to next test e.g. if gait speed not completed go to chair stand (as instructed in CRF).

**1. BALANCE TESTS**

The participant must be able to stand unassisted without the use of a cane or walker. You may help the participant to get up.

***Now let's begin the evaluation. I would now like you to try to move your body in different movements. I will first describe and show each movement to you. Then I'd like you to try to do it. If you cannot do a particular movement, or if you feel it would be unsafe to try to do it, tell me and we'll move on to the next one. Let me emphasize that I do not want you to try to do any exercise that you feel might be unsafe.***

***Do you have any questions before we begin?***

**a) Side-by-Side Stand**

1. ***Now I will show you the first movement***.
2. (Demonstrate) ***I want you to try to stand with your feet together, side-by-side, for about 10 seconds.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the side-by-side position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

**b) Semi-Tandem Stand**

1. ***Now I will show you the second movement***.
2. (Demonstrate) ***Now I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the semi-tandem position
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

## Short Physical Performance Battery (SPPB)

***All of the tests should be performed in the same order as they are presented in this CRF. Instructions to the participants are shown in bold italic and should be given exactly as they are written in this script. Please refer to instructions on facing page.***

**1.Balance Tests** ***please tick only one per test; leave other fields blank***

### a) Side-by-side Stand

Held for 10 sec ☐ **→Go to Semi-tandem Stand (below)**

Not held for 10 sec ☐ Number of seconds if less than 10 sec: ☐ . ☐

Not attempted ☐

***If participant did not attempt test or failed to hold for 10 sec, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

***→Go to Gait Speed Test (next page)***

### b) Semi-tandem Stand

Held for 10 sec ☐ **→Go to Tandem Stand (following page)**

Not Held for 10 sec ☐ Number of seconds if less than 10 sec: ☐ . ☐

Not attempted ☐

***If participant did not attempt test or failed to complete, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

***→Go to Gait Speed Test (next page)***

### c) Tandem Stand

1. ***Now I will show you the third movement***.
2. (Demonstrate) ***Now I want you to try to stand with the heel of one foot in front of and touching***

***the toes of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.***
3. ***You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.***
4. Stand next to the participant to help him/her into the tandem position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

**2. GAIT SPEED TEST**

**Mark out a 3 metre walking course.**
***Now I am going to observe how you normally walk. If you use a cane or other walking aid and you feel you need it to walk a short distance, then you may use it.***

**a) First Gait Speed Test**
1. ***This is our 3 metre walking course. I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store.***
2. Demonstrate the walk for the participant.
3. ***Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?***
4. Have the participant stand with both feet touching the starting line.
5. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
6. Press the start/stop button to start the stopwatch as the participant begins walking.
7. Walk behind and to the side of the participant.
8. Stop timing when one of the participant's feet is completely across the end line.

**b) Second Gait Speed Test**
1. ***Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.***
2. Have the participant stand with both feet touching the starting line.
3. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
4. Press the start/stop button to start the stopwatch as the participant begins walking.
5. Walk behind and to the side of the participant.
6. Stop timing when one of the participant's feet is completely across the end line.

## SPPB continued

**c)Tandem Stand**

Held for <3.00 sec ☐ →***Go to Gait Speed Test (below)***

Held for 3.00 to 9.99 sec ☐ →***Go to Gait Speed Test (below)***

Held for 10 sec ☐ →***Go to Gait Speed Test (below)***

Not Attempted ☐

***If participant did not attempt test, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

→***Go to Gait speed test***

**2. Gait Speed Test**

**a) Gait Speed Test 1**

Not attempted/not able ☐

***If participant did not attempt test or failed to complete, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

→**Go to Chair Stand (next page)**

Gait Speed time 1 ☐☐ . ☐ seconds

→***Repeat Gait Speed Test***

**b) Gait Speed Test 2**

Not attempted/not able ☐ →**Go to Chair Stand (next page)**

***If participant did not attempt test or failed to complete, please select reason from list below:*** ☐

If other (6) please specify……

1. Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

Gait Speed time 2 ☐☐ . ☐ Seconds →**Go to Chair Stand (next page)**

**3. CHAIR STAND TEST**

**Single Chair Stand**

1. ***Let's do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms?***
2. ***The next test measures the strength in your legs.***
3. (Demonstrate and explain the procedure.) ***First, fold your arms across your chest and sit so that your feet are on the floor; then stand up keeping your arms folded across your chest.***
4. ***Please stand up keeping your arms folded across your chest.*** (Record result).
5. If participant cannot rise without using arms, say ***"Okay, try to stand up using your arms."*** This is the end of their test. Record result.

**Repeated Chair Stands**

1. ***Do you think it would be safe for you to try to stand up from a chair five times without using your arms?***
2. (Demonstrate and explain the procedure): ***Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. I'll be timing you with a stopwatch.***
3. When the participant is properly seated, say: ***"Ready? Stand"*** and begin timing.
4. Count out loud as the participant arises each time, up to five times.
5. Stop if participant becomes tired or short of breath during repeated chair stands.
6. Stop the stopwatch when he/she has straightened up completely for the fifth time.
7. Also stop:

• If participant uses his/her arms
• After 1 minute, if participant has not completed rises
• At your discretion, if concerned for participant's safety

8. If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking ***"Can you continue?"***
9. If participant says "Yes," continue timing. If participant says "No," stop and reset the stopwatch.

| Participant ID | | | | | |
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## SPPB continued

**Single Chair Stand Test**

**Results:**

Participant stood without using arms ☐ **→Go to Repeated Chair Stand Test**

Participant used arms to stand ☐ **→End Test**

Test not completed ☐ **→End Test**

***If participant did not attempt test or failed to complete, please select reason from list below:*** ☐

If other (6) please specify……

1.Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

**Repeated Chair Stand Test**

Five stands completed Yes ☐ No ☐ **→End Test**

If five stands done successfully record the time in seconds

Time to complete five stands: ☐☐.☐ seconds

***If participant did not attempt test or failed to complete, please select reason from list below*** ☐

If other (6) please specify……

1.Tried but unable
2. Participant could not hold position unassisted
3. Not attempted, you felt it was unsafe for the participant
4. Not attempted, participant felt unsafe
5. Participant unable to understand instructions
6. Other (specify)
7. Participant refused

**Six-minute walk test INSTRUCTIONS**

**Instructions to the participant are shown in bold italic and should be given as they are written.**

With the participant sitting explain ***'We are interested in how far you can comfortably walk in 6 minutes, at you usual speed and using your walking aid as needed (if relevant). I will ask you to walk up and down the corridor. You can slow down, stop and rest as needed, but start walking again as soon as you are able. I will record each time you cross the starting line. You should turn around the cones and continue back the other way without hesitation. Now I'm going to show you'.***

Demonstrate by walking one lap yourself. Turn around the cone briskly.

Ask participant to stand up next to the starting line. ***'Are you ready? The aim is to walk AS FAR AS POSSIBLE for 6 minutes, but don't jog or run. Please walk up and down the corridor, around the cones for the next 6 minutes. Walk at your usual speed and try to walk as far as possible. Use your walking aid as needed (if relevant). If you need to stop and rest tell me and you can sit down. I will walk behind you so as not to affect your walking speed. Please start when you are ready'.***

**Equipment needed**

1. A 30 metre, pre-measured flat walking area with interval markings every three metres.
2. Cones or brightly coloured tape to mark boundaries of the course
3. Watch or timer to time 6 minutes
4. Chair available if patients need to rest during testing
5. Temporary marker to mark and measuring tape measure finish point
6. A source of oxygen
7. BP machine or Sphygmomanometer & Stethoscope
8. Telephone
9. Automated electronic defibrillator

**Absolute contraindications for the 6MWT include the following:**

Unstable angina during the previous month and myocardial infarction during the previous month.

**Relative contraindications include**

A resting heart rate of more than 120,

A systolic blood pressure of more than 180 mm Hg, and a diastolic blood pressure of more than 100 mm Hg.

**Participant preparation**

6. Comfortable clothing and appropriate shoes for walking should be worn.
7. Patients should use their usual walking aids during the test (cane, walker, etc.).
8. The patient's usual medical regimen should be continued.
9. A light meal is acceptable before early morning or early afternoon tests.
10. Patients should not have exercised vigorously within 2 hours of beginning the test.

**Reasons for immediately stopping a 6MWT**

(1) Chest pain, (2) intolerable dyspnoea, (3) leg cramps, (4) staggering, (5) diaphoresis, and (6) pale or ashen appearance.

Testing should be performed in a location where a rapid, appropriate response to an emergency is possible.

The appropriate location of a crash cart/trolley should be determined by the physician supervising the facility.

Supplies that must be available include oxygen, sublingual nitro-glycerine, aspirin, and metered dose inhaler or nebulizer. A telephone or other means should be in place to enable a call for help. The technician should be certified in cardiopulmonary resuscitation with a minimum of Basic Life Support. Advanced cardiac life support certification is desirable. Training, experience, and certification in related health care fields (registered nurse, registered respiratory therapist, certified pulmonary function technician, etc.) are also desirable. A certified individual should be readily available to respond if needed. Physicians are not required to be present during all tests. The physician ordering the test or a supervising laboratory physician may decide whether physician attendance at a specific test is required. If a patient is on chronic oxygen therapy, oxygen should be given at their standard rate or as directed by a physician or a protocol.

**Questionnaires –** this list is a checklist only, and not entered into OpenClinica

| Participant ID | | | | | |
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## Six minute walk test

Test completed without stops? Yes ☐ No ☐

Distance walked ☐☐☐ metres

If less than six minutes walked, please record time ☐ : ☐☐ minutes

If "No" please select reason from list below: ☐

1. Chest pain
2. Intolerable dyspnoea
3. Leg cramps
4. Staggering
5. Diaphoresis
6. Pale or ashen appearance
7. Participant refused

## Questionnaires

| Please indicate completion | | | | | |
|---|---|---|---|---|---|
| Oral Iron use scale | Yes | | No | | |
| Fatigue Severity Scale | Yes | | No | | |
| Patient Reported Anaemia Symptoms Month 1 | Yes | | No | | |
| Patient Reported Anaemia Symptoms Month 2 | Yes | | No | | |
| Patient Reported Anaemia Symptoms Month 3/follow up | Yes | | No | | |
| EQ-5D-5L™ | Yes | | No | | |
| 15D© | Yes | | No | | |
| Nottingham EADL© | Yes | | No | | |
| Health & Care Use | Yes | | No | | |
| Participant Experience | Yes | | No | | |

**Blood Sample Results**

Please enter only one digit in one box. Data should be entered at the right hand margin. If not enough digits are available to fill all fields, please prefix the number by recording “0”.

E.g. 19 would be entered as

| | | |
|---|---|---|
| 0 | 1 | 9 |

Where Haemoglobin and/or Ferritin samples are not taken leave the results field blank.

Ferritin results reported with a decimal place will be rounded:

- Where 0.4 and below round down e.g. 28.4 record as 28
- Where 0.5 and above round up e.g. 28.5 record as 29

| Participant ID | | | | | |
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## Adverse Events

**Experienced any adverse events (AE) since Visit 2?** **Yes** ☐ **No** ☐

**If "Yes" please add to AE Log**

## Iron preparations

**Please record details of all iron preparations in the Iron treatment Excel spreadsheet**

## Concomitant Medication

**Has the participant started any new medication since their last visit?** **Yes** ☐ **No** ☐

**If "Yes" please record all current medications in Concomitant Medication Form**

## Bloods

Haemoglobin sample taken? **Yes** ☐ **No** ☐

Ferritin sample taken? **Yes** ☐ **No** ☐

## Blood sample results

Haemoglobin ☐☐☐ g/L

Ferritin ☐☐☐ ug/L

| Participant ID | | | | | |
|---|---|---|---|---|---|
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## Completion of Trial /Early Withdrawal Form

Was the participant randomised? Yes ☐ No ☐

Did the participant attend the last study visit (Visit 4)? Yes ☐ No ☐

Date of completion/withdrawal D D – M M – Y Y Y Y

If subject was not randomised or did not complete the study, what was the main reason?

| **Reason** | | **Details** |
|---|---|---|
| Failed Eligibility (Screen fail)/ineligible | | N/A |
| Participant choice | | |
| No longer eligible (i.e. developed an exclusion) | | |
| On advice of PI/PI decision | | |
| Advice from GP/ other healthcare professional | | |
| Adverse event | | |
| Died | | N/A |

**Recording Adverse Events**.

AEs and SAEs will be recorded from the time of written informed consent until the last study visit.

- Only AEs which have resulted in the participant seeking advice or treatment from a healthcare professional will be recorded.
- The PI or delegate will ask about the occurrence of AEs and hospitalisations at each and every study visit.
- AEs will be assessed by the PI / medically qualified delegate for:
  severity, causality and seriousness.

NOTE: Reference safety information, Summary of Product Characteristics, for each of the oral and IV iron preparations are provided via the RAINDroP website.

- Once the Investigator becomes aware that an AE or SAE has occurred in a study participant, they must enter the information into the CRF AE Log and entered (in a timely fashion) into the OpenClinica database.
- Participants with unresolved AEs at the last study visit will be followed up until resolution or 30 days after their last study visit, whichever is sooner.

A serious adverse event (SAE) is defined as an untoward occurrence that:

(a) Results in death;

(b) is life-threatening;

(c) requires hospitalisation or prolongation of existing hospitalisation;

(d) results in persistent or significant disability or incapacity;

(e) consists of a congenital anomaly or birth defect; or

(f) is otherwise considered medically significant by the investigator.

Note: Hospitalisations for treatment planned prior to randomisation and hospitalisation for elective treatment of a pre-existing condition will not be considered as an SAE. However, any adverse events occurring during such hospitalisation will be recorded. See Protocol Section 10.1.1 for further AE and SAE reporting exemptions

**AE page completion**
Complete page No ….of ….. when all AEs have been entered.
If no AEs enter participant ID and initials and cross out page, then complete page No ….of ….. as No 1 of 1
Additional AE pages (unused) need not be completed / crossed-out.

| Participant ID | | | | | |
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RAndomised IroN Deficiency anaemia management Pilot

## ADVERSE EVENT LOG

| **Diagnosis** | **Date of onset** | **Date reported to Investigator team** | **Severity**<br>1. Mild<br>2. Moderate<br>3. Severe | **Causality**<br>1. Unrelated<br>2. Possible<br>3. Probable<br>4. Definite | **Action taken – please list all that apply**<br>1. None<br>2. Hospitalisation<br>3. Intervention stopped<br>4. Con meds commenced<br>5. Other (specify) | **Outcome**<br>1. Recovered<br>2. Recovered with sequelae<br>3.Ongoing<br>4. Disability or incapacity<br>5. Death<br>6. Unknown | **Is this a Serious AE?**<br><br>**YES/NO** | **If a SAE, is this reportable according to study protocol?**<br><br>**YES*/NO** | **Date resolved**<br>(Enter date resolved/date of death or tick if ongoing 30 days after end of study) | **Signature and Date**<br>PI or delegated doctor |
|---|---|---|---|---|---|---|---|---|---|---|
| *complete an SAE form and email to the phyo.myint@abdn.ac.uk , cc RAINDroPTM@dundee.ac.uk | | | | | | | | | | |
| | __/__/__ | __/__/__ | | | | | | | ___/___/___or ☐ | ___/___/___ |
| | __/__/__ | __/__/__ | | | | | | | ___/___/___or ☐ | ___/___/___ |
| | __/__/__ | __/__/__ | | | | | | | ___/___/___or ☐ | ___/___/___ |
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| Participant ID | | | | | |
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**Concomitant Medications**

Please record **only** concomitant medications that the participant is currently taking at Visits 1 and 4. Please use generic name. Start date, dose and frequency are not required.

- Following completion of Visit 4 assessments iron treatment taken between Visit 1 and Visit 4 are collected. Generic name, dose, unit and frequency are collected and recorded on the separate iron treatment excel spreadsheet.
- All other prescribed medications that are taken at the time of Visit 4 are recorded using the generic name, on the Concomitant Medication page of the CRF:
  - Concomitant Medication taken after Visit 1 and before Visit 4 are not recorded, e.g. antibiotics.
  - Over-the-counter medications are not recorded
  - Ingredients of combined medications should be listed separately

  e.g. for Co-dydramol list codeine and paracetamol.
  - Abbreviations should not be used.

**Concomitant Medication page completion**

Complete page No ….of ….. when all medications have been entered.
If no medications enter participant ID and initials and cross out page, then complete page No ….of ….. as No 1 of 1
Additional concomitant medication pages (unused) need not be completed / crossed-out.

| Participant ID | | | | | |
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**CONCOMITANT MEDICATIONS LOG**

| **GENERIC NAME OF DRUG**<br>**No iron preparations to be listed; complete iron treatment log and Excel spreadsheet at end of V4** | **Tick if patient is taking** | |
|---|---|---|
| | **Visit 1** | **Visit 4** |
| | ☐ | ☐ |
| | ☐ | ☐ |
| | ☐ | ☐ |
| | ☐ | ☐ |
| | ☐ | ☐ |
| | ☐ | ☐ |
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| NAME OF DRUG<br>No iron preparations to be listed; complete iron treatment log and spreadsheet at end of V4 | Tick if patient is taking | |
|---|---|---|
| | Visit 1 | Visit 4 |
| | ☐ | ☐ |
| | ☐ | ☐ |
| | ☐ | ☐ |
| | ☐ | ☐ |
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