RAINDroP: RAndomised IroN Deficency anaemia Pilot trial

Participant Information Sheet

We ask you to consider taking part in a research study about how we treat anaemia. Before you decide, you need to know why the study is being done and what you would have to do.

Please take time to read this information carefully and do not hesitate to ask if there is anything that is not clear or if you would like more information.

Why have I been invited?

You have been invited to take part because you have been treated with oral iron (tablets or liquid medicine) for your anaemia and your most recent blood test suggests that you may be eligible to participate.

Researchers have found that having anaemia is associated with symptoms of tiredness. This can make daily activities more difficult, and in turn lower quality of life for some people. Research also suggests that taking oral iron may not be effective for some older people.

Why are we doing the study?

When anaemia has not improved after a few weeks of oral iron, doctors do not know the best course of action. Should we carry on with oral iron, change to using iron given through a drip, or just stop iron altogether? Different

doctors recommend different approaches, but there is no clear guidance on the best course of action.

To find out the answers to these questions, we need to do clinical trials. We are running this small trial to test whether doing a bigger trial would be successful. Doing this small ('pilot') trial will show us which options are worth testing in a big trial. It will also show us the best way of finding and recruiting people for the big trial, and will allow us to test whether the measurements we take are important and relevant to older people.

Do I have to take part?

No. It is up to you to decide – you do not have to take part. The study doctor, or research nurse will discuss the study with you once you have read this information sheet; you will have an opportunity to ask any questions you want. If you agree to take part, someone from the RAINDroP trial team will ask you to sign a consent form. You can change your mind and you are free to leave the study at any time without giving a reason. This will not affect the standard of care you receive. If you, Dr Cvoro or one of your clinicians decides you should withdraw from the study, we would like your permission to retain and analyse the data already collected.

What will I have to do if I take part?

We will ask you to attend a research clinic twice – once at the start and then three months later. Each visit will take approximately one to two hours. We can arrange a taxi or we can pay for your travel expenses.

At each visit you will see a Research Nurse.

<u>At the first and last visits we will:</u>

- Record what medical problems you have and what medicines you take
- Check your height and weight (Visit 1 only)
- Ask you about tiredness, dizziness, breathing and your daily activities, your quality of life and any contact you have had with health workers such as nurses or your GP. At the last visit we will also ask you what you thought about taking part in the study
- Test your balance
- Ask you to walk over a short course (4 metres)
- Ask you to walk as far as you can up and down a corridor for six minutes, at your own pace. You can rest as often as you want when you do this, and you can use a stick or other walking aid if you wish to.

Please wear comfortable clothing and appropriate shoes.

- Finally we will take a blood sample (about a tablespoon). The blood taken will be tested in the local NHS laboratory. We will use standard tests to find out about your anaemia (haemoglobin, ferritin levels and c-reactive protein levels) and to assess your kidney function (creatinine and estimated GFR). We will only measure haemoglobin and ferritin at the last visit.

We will use results from blood tests that your GP has taken to decide if you are eligible to take part, however if these were taken over a year ago we will use the blood results from your first study visit. If you are not eligible we will either tell you at the visit or if we have to wait for the results we will telephone you soon after the visit; no further study visits will be required if you are not eligible.

No samples will be stored for future research. Blood samples are not taken for genetic testing.

<u>Visit 2, telephone call:</u>

A couple of days after Visit 1, you will receive a telephone call from a different research nurse who will tell you which treatment group you will be in.

You have an equal chance of being allocated to one of three groups:

- *Continue oral iron as usual*: Your GP will continue to prescribe oral iron as usual and all you need to do is to carry on taking them. We will write to your GP to tell them this.
- *Stop taking oral iron*: We will ask you to stop taking the iron tablet or liquid for whole study period and will write to your GP to ask them to stop prescribing the oral iron.
- *Intravenous Iron*: We will ask you to stop taking oral iron for 3 months and we will write to your GP to ask them to stop prescribing oral iron for 3 months. The research nurse will organise a separate visit within 2 weeks of the telephone call for you to receive the iron drip.

If possible, you should not tell the research nurse who you see at the last visit which treatment you have received.

Visit 3 is only if you receive IV iron:

At this visit you will be given iron by a drip directly into the vein. This will take place either at a local day hospital or research ward; the research nurse who telephoned you will be with you during this visit. This visit should not take more than 1 & 1/2 hours in total – about half an hour for the drip to run, and then an hour to rest and make sure that you do not suffer any side-effects. Some people may need a second drip a week later, depending on your weight and how anaemic you are.

Will taking part in the study affect my usual care?

Yes, the treatment for your anaemia will change during the study (described above). However we will not alter any of your other medication or interfere with your other treatment. You will continue to be seen by your GP and by any hospital clinics that you usually attend. We ask you to remind any doctor prescribing you a new medication that you are on the trial. If you are started on any new medications or if there are any changes to your health please inform the research team at the last study visit.

After you finish the study your GP will carry on, the care of your anaemia. We will advise you to contact your GP to arrange your medication.

With your agreement, at the end of the study we will check electronic information about how often you have visited your doctors (GP and hospital), and what medicines you have been prescribed.

With your agreement, we may contact you in the future to invite you to take part in more research.

Will my General Practitioner be informed of my study participation?

Your GP will be required to know what group you are allocated to and therefore we will need to tell your GP that

you are taking part. Your GP will be able to review your blood results from the tests that are taken during the study, these results can be used to plan your care when you finish taking part.

What are the possible benefits of taking part in this study?

We do not know if his study will help you directly but your participation will help us to provide the best care for people like you with anaemia due to low iron levels in the future.

What disadvantages are there?

Your health will be closely monitored by the research team. You will need to come to the hospital for two or three extra visits, but we will make these visits as short as possible and your travel costs will be reimbursed.

The physical assessments may make you feel a little tired. A nurse will be with you during the whole assessment and you will be able to rest between and after the assessments.

You will have additional blood tests (up to a maximum of 3 depending on which group you are allocated to) which can be slightly uncomfortable and/or cause bruising. The blood tests will be taken by an experienced member of staff.

Oral iron can cause constipation or a feeling of sickness in some people. If you are allocated to stop oral iron, it is unlikely that will have any disadvantage as your anaemia

has not improved satisfactorily so far. You may feel better as you will not have any side effects from taking oral iron.

If you are allocated to iron given into the vein (by a 'drip') this requires us to place a small needle in the vein, which may be slightly uncomfortable and/or cause a bruise. Experienced staff will insert the needle and monitor you closely while the iron drip is given. Iron given by a drip is already used commonly in the NHS, however it can on rare occasions cause an acute allergic reaction. If this does happen, fully trained medical and nursing staff will be on hand to treat you.

OTHER IMPORTANT INFORMATION

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time and you do not need to give reason. Only anonymised study will be retained following withdrawal. With your agreement, study data already collected from you will be used however if you choose we will not use your data.

The personal information that you provided so that the study team can contact you will be retained securely at the Health Informatics Centre, University of Dundee.

How will my information be kept confidential?

All the information that is collected about you during the course of this study will be kept strictly confidential. Identifiable information will be kept either electronically (access only via password) within a secure University of Aberdeen and/or Dundee system, or NHS system or paper records stored in a locked room.

There will be four sets of information obtained during the study:

- Personal information that you provide so that the study team can contact you. Personal information

will be held securely at the Health Informatics Centre, University of Dundee.

- Routine blood tests analysed by local NHS laboratories. The routine blood test results obtained will be stored indefinitely using your name and unique hospital record number within the NHS clinical system and can be made available to specialist doctors for your future health care needs. The research team will record your study visits in your hospital medical record.
- Research data obtained by the research team from your medical record and research study procedures. Your research data will be stored using a unique study code which is non-identifiable.
- Routine NHS Fife prescription, hospital and GP visit and social care use data will be collected at the end of the study. We will use this data to check research data that we have collected from you. This will be stored using your unique study code which is non-identifiable.

Any web-based data will be stored in a secure password protected central database at Health Informatics Centre, University of Dundee. Only individuals directly involved with the study will have access to this information.

The University of Aberdeen is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen will keep identifiable information about you for 15 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information http://www.abdn.ac.uk/privacyand/or by contacting Iain Gray, Aberdeen University Data Protection Officer.

NHS Fife will use your name, NHS number, date of birth and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the University of Aberdeen, University of Dundee and regulatory organisations may look

at your medical and research records to check the accuracy of the research study. NHS Fife will pass these details to the University of Aberdeen and University of Dundee along with the information collected from you and/or your medical records. The only people in the University of Aberdeen and University of Dundee who will have access to information that identifies you will be people who need to contact you to invite you to participate in the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, date of birth or contact details.

It is a requirement of the regulators that your records in this study, together with any other relevant medical records, be made available for scrutiny by appropriate monitors from University of Aberdeen and the Regulatory Authorities. This procedure is routine and carried out by fully qualified officials, and data confidentiality is preserved.

The University of Aberdeen and the University of Dundee will collect information about you for this research study from your medical records. NHS Fife will not provide any identifying information about you to the University of Aberdeen. We will use this information for this research study.

NHS Fife will keep identifiable information about you from this study for 15 years after the study has finished. At the end of the study the confidential records will be kept for 15 years and then destroyed. The confidential handling, processing, storage and disposal of data are in accordance with the General Data Protection Regulations.

No identifiable information will be used to report the findings.

What will happen to the results of this study?

The results of the study will help us to design a larger study. Current study results may be of public interest and in such case, we will aim to publish it in an academic journal and also plan to present the finding at the scientific meetings.

We will send you a summary of the final study results at the end of the trial (in early 2020), and we will share your individual results with you if you wish to see these. If you have access to the internet you can log onto the study's website; www.raindrop.org.uk for updates.

Information collected in this trial will be used to support other research in the future, and may be shared anonymously with other researchers. Information about you may also be inspected by regulators and funders who regulate clinical research.

Who is organising and funding this study?

The study is funded by the Chief Scientist Office of the Scottish Government.

How have patients and the public been involved in this study?

We have consulted patients with anaemia in designing this study, and a patient will be part of the committee advising us on the running and analysis of the trial. We have regular engagement with patients and public through our public engagement activities, and we will give you a summary of the results at the end of the trial.

What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your research doctor will arrange for your care to continue. If you decide to continue in the study, you will be asked to read a new information sheet and sign an updated consent form.

In addition, on receiving new information your research doctor might consider it to be in your best interests to

withdraw you from the study. He/she will explain the reasons and arrange for your care to continue

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions 01592 643355. You can ask to speak to a senior member of the research team or call the Complaints Officer for NHS Fife 01592 648153 ext 28153.

If you remain unhappy and wish to complain formally, you can do this by contacting 01592 648153; between 8.30am - 5.00pm Monday to Friday.

You can make a general enquiry, provide feedback or make a complaint by either:

Visiting the patient relations office at Hayfield House, within the grounds of Victoria Hospital, Kirkcaldy.

Telephoning us directly on: 01592 648153. Ext: 28153

Emailing us at: patientrelations.fife@nhs.net

Writing to us at: Patient Relations Department, Fife NHS Board, Room 104, Hayfield House, Hayfield Road, Kirkcaldy KY2 5AH.

If you have a hearing impairment you can contact us by SMS text number 07805 800 005 (Mon-Fri 8am to 4pm).

If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms (or equivalent University complaints mechanisms) should be available to you.

Who has reviewed this study?

The North of Scotland Research Ethics Committee (1) has reviewed the study protocol and approved the study.

Further information and contact details

If you would like further information contact details are available below.

Chief Investigator: Prof Phyo Myint

Research Nurse: Lisa Breckenridge 01592 643355