Participant Information Sheet Tayside
Professional Legal Representative

Trial title

SFX-01 **T**reatment for **A**cute **R**espiratory Infections (**STAR**-Covid19)

Trial Researcher

Professor James Chalmers

Why am receiving this information?

You are receiving this information because you are the professional legal representative of somebody who has been admitted to hospital with suspected COVID-19 and does not have capacity to decide for themselves whether to take part in this trial.

An individual's professional legal representative is a person not connected with the conduct of the trial who is:

- the doctor primarily responsible for the adult's medical treatment, or

- a person nominated by the relevant health care provider

This is allowed by the Adults with Incapacity Act (Scotland) 2000, Mental Capacity Act and Medicines for Human Use (Clinical Trials) Regulations.

We're inviting an individual who does not have capacity to consent for themselves to take part in a research trial

Before you decide whether to agree to the person for whom you are the professional legal representative taking part we want you to understand why we're doing the trial and what it will involve. Please take time to read this information carefully.

We are asking that you put your own views about the research aside. Based on your professional knowledge of the individual together with your knowledge about this trial we are asking you to consider whether to consent to this individual taking part in the trial.

You can ask the research team any questions you have and talk to other people about it if you want. We'll do our best to answer your questions and give you any information

you ask for. You don't have to decide straight away – but we would like to start the trial treatment as soon as possible.

Why are we doing this trial?

Patients who are admitted to hospital with suspected COVID-19 may have difficulties breathing. Many need oxygen and some need help to breathe (put on a ventilator) before they get better. However, a small number of people don't get better. Their lungs can over-react to the infection and become inflamed. Over time their lungs may gradually become more and more damaged.

A company in the UK, Evgen Pharma, have developed a drug called SFX-01 which we think might help people with suspected COVID-19. The drug isn't licenced for doctors to prescribe yet but the company has done trials using the drug to check that it is safe. We think that SFX-01 may help people with suspected COVID-19 by reducing the amount of inflammation and damage in their lungs. We want to know if taking SFX-01 shortens their time in hospital. We also want to find out if they are less likely to need oxygen for a long period or put on a ventilator and if they are more likely to recover.

What is being tested?

Each participant will get one SFX-01 capsule or one dummy capsule (placebo) every day for 14 days.

Whether they get the SFX-01 capsule or the dummy capsule will be decided randomly (like tossing a coin, but using a computer). Neither you nor their trial team will be able to decide if they get SFX-01 capsule or the dummy capsule. To take part in the trial you will need to be happy that they will be given either the SFX-01 capsule or the dummy capsule.

Why has the person I am consenting for been chosen?

The person you are being asked to consent for has been chosen to take part as they have been admitted to hospital with breathing problems that are suspected to be due to COVID-19. A total of 300 participants with suspected COVID-19 at different hospitals in the UK will take part in the trial. We are asking you, as their profesional legal representative, if you will allow them to be in the trial.

Does the person I am consenting for have to take part?

No. It is up to you to decide whether they take part in the research or not. If you choose that they do take part they can stop the trial at any time. You don't have to give a reason for choosing that they don't take part or for them stopping, and the medical care that they get and their relationship with the medical or nursing staff looking after them won't be affected.

What happens if the person I am consenting for gets better and is able to decide themself?

We'll ask them if they want to continue in the research trial and we'll give them a Participant Information Sheet to read. If they want to continue in the trial we'll ask them to fill out their own consent form.

What will happen to the person I am consenting for if they take part?

We'll check their medical notes to see if they're able to take part. We'll check what the nursing and medical staff looking after them have recorded about their condition and will look at the results of tests that they've had - for example blood tests, chest x-ray and CT scan. We'll also look at what medications they're already taking.

In this trial we will include people who have had a test for COVID-19. The test does not need to be positive for them to take part.

A member of the research team will speak to you about the trial and answer any questions you have. If you want them to take part, we'll ask you to fill out and sign a consent form. This will confirm that you understand what the trial means for them and that you agree to them taking part.

Will they need to have any other tests?

If they haven't had a blood test to check their kidneys, liver or blood count (haemoglobin) in the last 3 days we'll take a blood test to check this. We'll also check their blood pressure, pulse, temperature and oxygen levels from their finger if they haven't had these recorded in the last 24 hours. We expect that they'll have had these done already by the nurses or doctors looking after them and if that's the case we won't do them again.

What happens next?

Then we'll let you know if they're suitable to take part in the trial or not.

We'll use a computer to find out what bottle of capsules they have been allocated. Their doctors and nurses will not know if the bottle contains SFX-01 capsules or the placebo capsules. The nurse looking after them will give them one of the trial capsules every day along with any other medications that they have been prescribed while they're in hospital. They'll take the trial capsules for 14 days.

We'll check their medical notes every day while they're in hospital to see how they're getting on. We'll record these details for a maximum of 29 days. We will also take blood from them on 3 occasions (first day of treatment, day 7 and day 15). We will do tests on this blood to measure levels of inflammation and to work out whether the SFX-01 has been working in their body. We will also take a sputum sample or nose or throat swab so that we can test what type of infection they have.

If COVID-19 makes them very unwell during the trial and they can't take anything by mouth, they may have a tube put in by the clinical team which is passed through their nose and down into their stomach (this is called a nasogastric or NG tube). We won't put a NG tube in just for the trial, but if they have one, the nurse giving them their medications will dissolve the trial medicine in water and give it to them through their NG tube. We'll continue to look at their medical notes and collect their details for 29 days as described above.

If they leave hospital before the end of the treatment (14 days), we'll give them the trial capsules to take home to finish. We will also arrange for them to come in to the hospital for their 15 day blood test. We will reimburse any reasonable travel expenses for their visit.

We'll phone them a maximum of 6 times up to day 29 to ask you how they're getting on, if they've been unwell for any reason since leaving hospital and if any of their usual medications have been changed. When they leave hospital we'll give them a diary to fill in to write down if they have any new symptoms or feel unwell and if they have any

changes to their prescribed medications. We'll ask them about this when we phone them. We'll also give them a phone number so that they can call us if they need to.

When we collect the details about them and their condition, we save these on a computer but we'll not save their name or other personal details which would be able to identify them.

We'll keep their contact details separately, so if they leave hospital we can phone them.

Will taking part in the trial affect their usual care?

No, they'll get all the usual care by the nurses and doctors looking after them.

What will happen when the trial finishes?

They won't continue to get the trial medication when the trial finishes.

What are the possible benefits of taking part?

The trial may not immediately benefit them, but if the results of the trial are good this may improve how we treat people with pneumonia and COVID-19.

What are the possible disadvantages and risks of taking part?

SFX-01 is an un-licensed medicine but it's already been used in clinical trials. Trials with healthy people and those with particular types of cancer and stroke showed that the medicine was generally well tolerated by people in the trial.

The most common side effects reported were stomach pains and discomfort, indigestion, nausea and vomiting. These side effects can be lessened by taking the capsule with food. Also, diarrhoea was reported commonly in the previous clinical trial with cancer patients.

When they're in hospital they'll be closely monitored by the clinical team. We'll ask the clinical team to let us know if they have any worries about them taking the trial capsules. We'll also check their medical records frequently and we'll report any concerns to the trial doctors and their clinical team. If they leave hospital before the end of the 14 days treatment period we'll phone them as we said above.

Contraceptive advice

If they're a woman who could get pregnant and they're sexually active, they will have a pregnancy test before starting the trial. They must be willing to use 2 forms of medically approved birth control while they take the trial capsules and for 30 days after they take the last capsule.

If they're a man and are sexually active with a woman who could get pregnant, they must be willing to use 2 forms of medically approved birth control while they take the trial capsules and for 90 days after they take the last capsule.

We will discuss this with them.

Medically approved birth control methods:

- Combined Oral Contraceptive Pill
- Intrauterine device – 'coil'
- Injected, patch or implant contraceptive
- Male partner vasectomy - sterilisation

Who is organising and funding this research?

This trial is being sponsored by the University of Dundee and NHS Tayside. It is being funded by LifeArc and Evgen Pharma. The trial is being organised by Professor James Chalmers, University of Dundee.

What will happen with the information you collect about the person I am consenting for?

Their identifiable information (for example: their name, hospital number and telephone number) and the information we collect about them during the trial will be stored by their local research team. Only specified members of the research team can see this information.

Any information collected about them during the trial will be encoded by the research team so that their details will be anonymous. This means that their identifiable information will not be used. Their trial information will be securely stored on password protected databases managed by the University of Dundee. Some members of the data management team may also have access to your identifiable information to manage your information and maintain the database.

Their trial information will be kept securely for 25 years after the end of the trial. After 25 years it will be destroyed. This is a legal requirement for trials using medication.

If you'd like us to inform them about future trials that they might be interested in taking part in, we'll ask you to complete the optional section of the consent form to allow us to hold their contact details.

We'll ask your permission to tell their GP that they're taking part in this trial.

Their identifiable information will not be published or shared.

We may share their anonymous trial information with other researchers.

The Data Protection Privacy Notice section gives more information about this.

What if something goes wrong?

If you're concerned about their taking part in the trial, you have the right to discuss your concern with a researcher involved in carrying out the trial or a doctor involved in their care.

If you have a complaint about their participation in the trial, first of all you should talk to a researcher involved in the trial. You can also make a formal complaint. You can make a complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside by emailing: feedback.tayside@nhs.net

If you think they have come to harm due to taking part in the trial there aren't any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice but you might have to pay for your legal costs.

Insurance

The University of Dundee and Tayside Health Board are Co-Sponsoring the trial. The University of Dundee has a policy of professional negligence clinical trial insurance which gives legal liability cover and no fault compensation for accidental injury. Tayside Health Board is a member of the NHS Scotland Clinical Negligence and Other Risks Insurance Scheme (CNORIS) which gives legal liability cover of NHS Tayside for this trial.

As the trial involves University of Dundee staff carrying out clinical research on NHS Tayside patients, these staff hold honorary contracts with Tayside Health Board. This means they will be covered under Tayside's membership of the CNORIS scheme.

Other Scottish Health Boards are participating as trial sites and they are also members of CNORIS. This will cover their liability for carrying out the trial.

NHS Health Trusts in England are taking part as trial sites and they have membership of a scheme like CNORIS from the NHS Litigation Authority (NLA).

If they apply for health, life, travel or income protection insurance they may be asked questions about their health. These questions might include questions about any medical conditions they currently have or have had in the past. We don't expect that taking part in the trial will adversely affect your ability to buy insurance. Some insurers may use this information to limit the amount of cover, apply exclusions or increase the cost of insurance. Their insurer may take in to account any medical conditions they have, including any which are diagnosed as part of a research trial, when deciding whether to offer insurance to them.

Who has reviewed this trial?

This trial has been reviewed and approved by Scotland A Research Ethics Committee who are responsible for reviewing research which is carried out in humans. The Research Ethics committee doesn't have any objections to this trial going ahead.

Detail how patients and the public been involved in the trial

The Edinburgh Clinical Research Facility – Covid19 Patient Public Involvement Advisory Group have helped to write the information that we give to you.

Data Protection Privacy Notice

How will we use information about the person you are consenting for?

We'll need to use information from them and from their medical records for this research trial.

This information will include their initials, NHS number, name and contact details. Staff will use this information to do the research or to check their records to make sure that the research is being done properly.

People who don't need to know who they are will not be able to see their name or contact details. Their data will have a code number instead.

We'll keep all information about them safe and secure.

Once we've finished the trial, we'll keep some of the data so we can check the results. We'll write our reports in a way that no-one can work out that they took part in the study.

What are your choices about how the person you are consenting for's information is used?

- You can stop them being part of the trial at any time, without giving a reason, but we'll keep information about them that we have already collected.
- If you choose to stop them taking part in the study, we'd like to continue collecting information about their health from their hospital records. If you don't want this to happen, tell us and we'll stop.
- We need to manage their records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about them.

Where can you find out more about how the person you are consenting for's information is used?

You can find out more about how we use their information at:

- www.hra.nhs.uk/information-about-patients/
- http://www.ahspartnership.org.uk/tasc/for-the-public/how-we-use-your-information
- https://www.dundee.ac.uk/information-governance/dataprotection/
- http://www.nhstayside.scot.nhs.uk/YourRights/PROD_298457/index.htm
- or by contacting Research Governance, Tayside Medical Science Centre (TASC), 01382 383900 email tascgovernance@dundee.ac.uk

Contact details for further information.

Principal Investigator: Professor James Chalmers

Phone: 01382 386131

Email: j.chalmers@dundee.ac.uk

Research Nurse: Jennifer Taylor

Phone: 01382 632287

Email: jennifer.taylor4@nhs.scot

Thank you for taking time to read this information and for considering to provide consent for this individual with incapacity to take part in this trial.

If you'd like more information or want to ask questions about the trial, please contact the trial team using the contact details above.

You can contact us Monday – Friday between 09:00-17:00.

Outside of those hours, if you need advice you can contact your out-of-hours GP service/NHS24 via 111.

You can also contact: Dr Tom Fardon, tom.fardon2@nhs.scot, 01382 383915 if you want independent advice about taking part in the trial from someone who is not connected to the trial.