Participant Information Sheet Tayside
Recovered capacity

Trial title

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

Trial Researcher

Professor James Chalmers

You are being invited to consider continuing to take part in a research study.

Why am I already in this study?

During your admission to hospital you were unable to give consent for entry into a trial. We therefore asked your legal representative who gave consent on your behalf to enter this trial.

In Scotland your legal representative is your nearest relative, welfare attorney, welfare guardian or a doctor who is involved in your clinical care but is independent from the trial. This is allowed by the Adults with Incapacity Act (Scotland) 2000 and Medicines for Human Use (Clinical Trials) Regulations.

In England and Wales your legal representative is a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the you or a doctor who is involved in your clinical care but is independent from the trial. This is allowed by the Mental Capacity Act and Medicines for Human Use (Clinical Trials) Regulations.

We are inviting you to continue to take part in a research trial

Before you choose whether or not to continue to take part, we want you to understand why we're doing the trial. We also want to tell you what it will involve if you agree to continue. Please take time to read this information carefully. You can ask us 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 will continue with the trial until you decide.

Why are we doing this trial?

Patients who are admitted to hospital with pneumonia caused by infection with COVID19 or other bug often 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 pneumonia. 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 pneumonia by reducing the amount of inflammation and damage in their lungs. We want to know if taking SFX-01 shortens your time in hospital. We also want to find out if you're less likely to need oxygen for a long period or put on a ventilator and if you're 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 you get the SFX-01 capsule or the dummy capsule has been decided randomly (like tossing a coin, but using a computer). Neither you nor your trial team were able to decide whether you got SFX-01 capsule or the dummy capsule. To take part in the trial you will need to be happy to either take the SFX-01 capsule or the dummy capsule.

Why was I chosen?

You were chosen to take part as you were admitted to hospital with breathing problems that were suspected to be due to pneumonia. A total of 300 participants with pneumonia at different hospitals in the UK will take part in the trial.

Do I have to continue to take part?

No. Continuing to take part in this trial or not is entirely up to you. If you choose to take part you can stop the trial at any time. You don't have to give a reason for not taking

part or for stopping, and the medical care you get and your relationship with the medical or nursing staff looking after you won't be affected.

What will happen to me if I take part?

We checked your medical notes to see if you were able to take part. We checked what the nursing and medical staff looking after you recorded about your condition and we looked at the results of tests that you've had - for example blood tests, chest x-ray and CT scan. We also looked at what medications you're already taking.

In this trial we included people who had a test for COVID-19 to see if that was the cause of their pneumonia. The test did not need to be positive for you 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 to continue we'll ask you to fill out and sign a consent form. This will confirm that you understand what the trial means for you and that you agree to continue.

Did I need to have any other tests?

If you hadn't had a blood test to check your kidneys, liver or blood count (haemoglobin) in the 3 days before starting the trial we would have taken a blood test to check this. We also checked your blood pressure, pulse, temperature and oxygen levels from your finger if these hadn't been recorded in the 24 hours before starting the trial. We expect that you would have had these done already by the nurses or doctors looking after you and, if you had, we didn't do them again.

What happens next?

We used a computer to find out what bottle of capsules you were allocated. Your doctors and nurses didn't know if the bottle contains SFX-01 capsules or the placebo capsules. The nurse looking after you will continue to give you one of the trial capsules every day along with any other medications that you have been prescribed while you're in hospital. You'll take the trial capsules for 14 days.

We'll check your medical notes every day while you're in hospital to see how you're getting on. We'll record these details for a maximum of 29 days. You also had a sputum sample or nose or throat swab taken so that we can test what type of infection you

have. We will also take blood from you 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 your body.

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

If you leave hospital before the end of the treatment (14 days), we'll give you the trial capsules to take home to finish. We'll phone you a maximum of 6 times up to day 29 to ask you how you're getting on, if you've been unwell for any reason since leaving hospital and if any of your usual medications have been changed. When you leave hospital we'll give you a diary to fill in to write down if you have any new symptoms or feel unwell and if you have any changes to your prescribed medications. We'll ask you about this when we phone you. We'll also give you a phone number so that you can call us if you need to.

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

We'll keep your contact details separately, so if you leave hospital we can phone you.

Will taking part in the trial affect my usual care?

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

What will happen when the trial finishes?

You 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 you, but if the results of the trial are good this may improve how we treat people with pneumonia.

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

Contraceptive advice

If you're a woman who could get pregnant and you're sexually active, we will have done a pregnancy test before you started the trial. Only women who are not pregnant are included in the trial. You must be willing to use 2 forms of medically approved birth control while you take the trial capsules and for 30 days after you take the last capsule.

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

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 me?

Identifiable information about you and the information we collect about you during the trial will be stored by your local research team. Only specified members of the research team can see this information - for example: your name, hospital number and telephone number.

Any personal information which could identify you individually will be encoded by the research team so that your details will be anonymous. This means that your name or anything linked to your name will not be used (for example your hospital number). Your 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.

Your 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 you about future trials that you might be interested in taking part in, we'll ask you to agree by signing the optional section of the consent form to allow us to hold your contact details.

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

Information which identifies you personally will not be published or shared.

We may share your trial information with other researchers but any information which identifies you will be removed before we share it.

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

What if something goes wrong?

If you're concerned about 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 your care.

If you have a complaint about your 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 you 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 you apply for health, life, travel or income protection insurance you may be asked questions about your health. These questions might include questions about any medical conditions you 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. Your insurer may take in to account any medical conditions you have,

including any which are diagnosed as part of a research trial, when deciding whether to offer insurance to you.

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 you?

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

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

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

We'll keep all information about you 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 you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the trial at any time, without giving a reason, but we'll keep information about you that we have already collected.
- If you choose to stop taking part in the study, we'd like to continue collecting information about your health from your hospital records. If you don't want this to happen, tell us and we'll stop.

- We need to manage your 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 you.

Where can you find out more about how your information is used?

You can find out more about how we use your 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.

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Thank you for taking time to read this information and for considering taking 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.