



Trial title?

SFX-01 Treatment for Acute Respiratory Infections (STAR-Covid19)

What is the trial about?

Patients who are admitted to hospital with pneumonia and suspected Covid-19 may have difficulties breathing. Many need oxygen and some need help to breathe before they get better. In some cases the lungs can over-react to the infection and become inflamed. This damages the lungs and over time the damage gradually gets worse.

We think a drug called SFX-01 may help people with pneumonia and COVID-19 by reducing the amount of inflammation and damage to the lungs.

What is involved?

Participation in the trial is entirely voluntary and you may withdraw at any time. You'll be allocated to receive either SFX-01 (300mg daily for 14 days) or placebo in addition to standard of care. If you leave hospital before the end of the 14 days, we'll give you the trial tablets to take home to finish. We'll phone you 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. We'll do regular blood tests while you are on the trial medication, the last on day 15. If you've been discharged from hospital before this date then we'll arrange an appointment for you to have this done.

What are the possible benefits and risks of taking part?

By taking part you are contributing to medical science and the results may help other people in the future.

As of 30th March 2020, 134 subjects have been treated with SFX-01 across 4 clinical trials, two patient trials and two healthy volunteer trials. SFX-01 has been well tolerated with no safety concerns to date

Who has reviewed the trial?

The Scotland A Research Ethics Committee has looked at this study and has raised no objections from the point of view of medical ethics

Will my taking part in the trial be kept confidential?





Yes, 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.

The Star Trial

If you are interested in taking part in this trial or would like any more information please ask the nurse looking after you to contact the trial team

Or

Or

Call Research nurse: 01382 632287

Email: jennifer.taylor4@nhs.scot

We will discuss the trial further and answer any questions you have

Your local investigator for the trial is:

Principle Investigator: Professor James Chalmers Division of Cardiovascular Medicine, Level 5, Mailbox 12, Ninewells Hospital, Dundee, DD1 9SY 01382 383642

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The STAR Trial IRAS Ref number: 286251