

❖ The STOP-COVID19 Trial

If you are interested in your ward/relative/person, that you are consenting for, taking part in this trial or would like any more information please ask the nurse looking after them to contact the trial team.

Or



Call Researcher:
[LOCAL RESEARCHER]

Or



E-mail:
[LOCAL RESEARCHER]

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

❖ Will their taking part in the study be kept confidential?

Yes, 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.

STOP-COVID19 Brief Participant Information Sheet
Legal representative
V2 29-05-20

❖ Your local Investigator for the trial is:

Principal Investigator:

[LOCAL PI]
[ADDRESS]
[PHONE NUMBER]
[EMAIL]

LOCAL NHS LOGO

**STOP-
COVID19** | Superiority Trial
Of Protease
inhibition in
COVID-19

*Research to test a
new treatment for
COVID-19*

**Does your relative have
COVID-19?**

**They may be able to take part in
a research trial**

The STOP-COVID19 Trial

Superiority Trial of Protease
inhibition in COVID-19

IRAS Ref number: 281986



We're inviting you to choose whether or not to give your permission for your ward/relative/person that you are consenting for to take part in a research trial. The person you are consenting for is suitable to take part as they have been admitted to hospital because they may have COVID-19. At the moment they are not able to decide if they want to take part .

🔗 **What is the study about?**

About 8 out of 10 people who get COVID-19 get better without going to hospital. Most patients admitted to hospital get better, but most need oxygen and some need help to breathe (put on a ventilator) before they get better. But, a small number of people don't get better.

There are no drugs at the moment which we know will definitely help people with COVID-19. We are doing a research trial to test whether a new treatment is effective. This is a tablet called Brensocatib (INS1007) once per day for 28 days. Brensocatib reduced inflammation in the lungs of people with bronchiectasis. We think that it may help people with COVID-19.

🔗 **What is the study about? (cont.)**

We want to know if taking Brensocatib shortens your time in hospital, if you need oxygen for a shorter period or are less likely to need to be put on a ventilator and if you're more likely to recover.

Whether they get the Brensocatib tablet or the dummy tablet will be decided randomly (like tossing a coin).

🔗 **What is involved?**

Their participation in the trial is entirely voluntary and you may withdraw them at any time.

If they haven't had a blood test to check your 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 your 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 they have, we won't do them again.

We'll check their medical notes every day while you're in hospital to see how they're getting on. We'll record these details for a maximum of 29 days.

🔗 **What is involved? (cont.)**

If they leave hospital before the end of the 29 days, we'll give them the trial tablets to take home to finish. We'll phone you no more than 5 times in the next month. We'll ask them how you're getting on, if they've been unwell for any reason since leaving hospital and if any of their usual medications have been

🔗 **What are the possible benefits and risks of taking part?**

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

Brensocatib is an un-licensed medicine but it's already been used in clinical trials. Trials with healthy people and those with lung conditions (with over 250 people involved) showed that the medicine was generally well tolerated by people in the trial.

🔗 **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.