Participant Information Sheet

Recovered Capacity

Trial title

STOP-COVID19: **S**uperiority **T**rial **O**f **P**rotease inhibition in **COVID-19**

Trial Researcher

## Insert the name of the Site PI

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?

About 8 out of 10 people who get COVID-19 get better without going to hospital. Most patients admitted to hospital with COVID-19 get better, most 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.

There are only a couple of drugs at the moment which we know will definitely help people with COVID-19. A company in the USA, Insmed Inc., have developed a drug called Brensocatib (INS1007) which we think might help people with COVID-19. The drug isn’t licenced for doctors to prescribe yet but the company has done trials using the drug. The trials gave it to healthy people, to see if it was safe, and to people with a lung condition called bronchiectasis, to see if it helped control their symptoms (bronchiectasis is a lung condition which causes frequent chest infections and inflamation in the air passages). Brensocatib reduced inflammation in the lungs in people with bronchiectasis. We think that Brensocatib may help people with COVID-19 in a similar way to people with bronchiectasis. We want to know if taking Brensocatib 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 Brensocatib tablet or one dummy tablet (placebo) every day for 28 days.

Whether you get the Brensocatib tablet or the dummy tablet has been decided randomly (like tossing a coin, but using a computer). Neither the person consenting for you or your trial team were able to decide if you got Brensocatib or the dummy tablet. To take part in the trial you need to be happy to either take the Brensocatib tablets or the dummy tablets.

Why was I chosen?

You were chosen to take part as you were admitted to hospital with COVID-19. A total of 300 participants will take part in the trial at different hospitals in the UK.

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 continuing or for stopping. If you do not want to continue, 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 were already taking.

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 last 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.

We used a computer to find out what bottle of tablets you were allocated. Your doctors and nurses don’t know if the bottle contains Brensocatib tablets or dummy tablets. The nurse looking after you will continue to give you one of the trial tablets every day along with any other medications that you have been prescribed while you’re in hospital. You’ll take the trial tablets for 28 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.

If COVID-19 makes you 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 tablet 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 29 days we’ll give you the trial tablets to take home to finish. We’ll phone you no more than 5 times (on the 3rd, 5th, 8th, 15th and 29th day after you started the trial tablets). We’ll 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 you 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 will not 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 COVID-19.

What are the possible disadvantages and risks of taking part?

Brensocatib is an un-licensed medicine but it’s already been used in clinical trials. In 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.

The most common side effects reported were cough, increased phlegm, headache and breathlessness. These are common symptoms for people with lung conditions and they were also reported frequently by people taking the placebo tablets.

Two side effects that we know are possible with this medicine are thickening of the skin and inflammation of the gums, both of which happen rarely. We’ll ask you regularly if you’ve had any problems with skin or teeth during the trial.

When you’re in hospital you’lll 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 tablets. 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 29 days lwe’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 a birth control method which is medically approved until you finish the 28 days of the tablets.

If you’re a man and are sexually active with a woman who could get pregnant, you must be willing to use a birth control method which is medically approved while you take the trial tablets and for 30 days after you take the last tablet.

Medically approved birth control methods:

Combined Oral Contraceptive Pill

Intrauterine device – ‘coil’

Male condom

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 Insmed Inc. The trial is being organised by Professor James Chalmers, University of Dundee.

What will happen with the information you collect about me?

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

Any information collected about you during the trial will be encoded by the research team so that your details will be anonymous. This means that your identifiable information will not be used. Your trial information will be securely stored on databases with access restricted. The databases will be managed by the University of Dundee.

Your trial information will be kept securely for 25 years after the end of the trial. After 25 years it will be destroyed. This is normal legal requirement for all trials involving medicines. 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 complete the optional section of the consent form to allow us to hold your contact details.

We asked the person giving consent for you for permission to tell your GP that you’re taking part in this trial.

Your identifiable information will not be published or shared.

We may share your 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 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 [insert Site Name and Contact details below]

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 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.

## **How have 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/](https://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.**

*Insert email and telephone number for appropriate research staff at Site*

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: [NAME, EMAIL, PHONE NUMBER] if you want independent advice about taking part in the trial from someone who is not connected to the trial.