Participant Information Sheet

Legal Representative

Trial title

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

Trial Researcher

Professor James Chalmers, Consultant Respiratory Physician, Ninewells Hospital & Medical School, Dundee

We’re inviting you to choose whether or not to give your permission for your ward/relative/person to take part in a research trial. Before you decide 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 and to consider and take into account, the past and present wishes and feelings of the person who you are consenting for, had they been able to consent for themselves.

Please take time to read this information carefully and discuss it with others if you wish.

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 information. 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?

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 of people with bronchiectasis. We think that Brensocatib may help people with COVID-19 in a similar way. We want to know if taking Brensocatib shortens someone’s time in hospital. We also want to find out if people are less likely to need oxygen for a long period or put on a ventilator and if people are 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 participants get the Brensocatib tablet or the dummy tablet 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 Brensocatib or the dummy tablets. To take part in the trial you will need to be happy that they will be given either the Brensocatib tablets or the dummy tablets.

Why has the person I am consenting for been asked?

The person you are consenting for has been asked 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. A total of 300 participants with COVID-19 at different hospitals in the UK will take part in the trial. We are asking you, as their legal representative, if you will allow them to be in the trial.

In Scotland a 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 a 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.

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 take part you can stop the trial at any time. You don’t have to give a reason for them not taking part or for 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 will give them a Participant Information Sheet to read. If they want to continue in the trial we will 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.

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.

Then we 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 tablets they have been allocated. Their doctors and nurses will not know if the bottle contains Brensocatib tablets or dummy tablets. The nurse looking after them will give them one of the trial tablets every day along with any other medications that they have been prescribed while they’re in hospital. They’ll take the trial tablets for 28 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.

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 tablet 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 a total of 29 days as described above.

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 no more than 4 times (on the 3rd, 5th, 8th and 15th day after they you started the trial tablets). We’ll ask them 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.

We’ll ask to see them on the 29th day after they started to take their tablets. This visit will be either in the hospital or at their home. We’ll arrange a taxi or pay for travel expenses if they come to the hospital. At this visit we’ll check their blood pressure, pulse and temperature and oxygen levels from their finger. We will also take blood and sputum samples and a nose swab to test for COVID-19. We’ll also ask how they have been getting on like we’ll do when we phone them.

In total we’ll take four extra blood samples and sputum samples and two extra nose swabs to test for COVID-19. These samples will be obtained at the same time as any clinical samples are being taken to monitor their condition. These samples will be used by the scientists at the University of Dundee for research into how their body responds to COVID-19 and the trial drugs.

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 will 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 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 them, but if the results of the trial are good this may improve how we treat people with 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. 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 them regularly if they’ve had any problems with skin or teeth during the trial.

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 tablets. 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 29 days we will phone them as we said above.

Contraceptive advice

If they are 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 a birth control method which is medically approved until they finish the 28 days of the tablets.

If they are a man and are sexually active with a woman who could get pregnant they 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.

We will discuss this with them.

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 collected 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 (trial information) 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 databases with restricted access. The databases will be managed by the University of Dundee.

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 normal legal requirement for all trials involving medicines. 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 theconsent 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, Complaints and Feedback Team

Ninewells Hospital

Dundee

DD1 9SY

tay.feedback@nhs.scot or 0800 027 5507

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 have or have had in the past. We don’t expect that taking part in the trial will adversely affect their 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 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 the person you are consenting for?

We’ll need to use information that you give to us 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 them 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/](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.**

Principal Investigator: Professor James Chalmers

Phone: 01382 386131

Email: j.chalmers@dundee.ac.uk

Research Nurse: Lesley Smith

Phone 01382 383687

Email tay.respiratoryresearch@nhs.scot

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.

Thank you for taking time to read this information and for considering to consent for your ward/relative/person 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.