

Will my taking part in the study be kept confidential?

In this research study we will use information from you and your medical records. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the trial, we will save some of the data in case we need to check it and for future research. We will make sure no-one can work out who you are from the reports we write.

The Participant Information Sheet tells you more about this.

The GREAT-2 Trial

If you are interested in taking part in this trial or would like any more information, please contact the trial team by:



Calling Researcher:

[LOCAL RESEARCHER]

Or



E-mail: [LOCAL RESEARCHER]

We will discuss the trial further and send you a full information sheet.

Your local Investigator for the trial is:

Principal Investigator:

[LOCAL PI]

[ADDRESS]

[PHONE NUMBER]

[EMAIL]

LOCAL NHS LOGO



Research to test a new treatment for infection in bronchiectasis.

Do you have bronchiectasis?

You may be able to take part in a research trial

The GREAT-2 trial

Gremubamab compared to placebo in participants with bronchiectasis and chronic *Pseudomonas aeruginosa* infection

What is the trial about?

People with bronchiectasis frequently get chest infections which are difficult to treat. Approximately one third of people with bronchiectasis become infected with a bacteria called *Pseudomonas aeruginosa* (*P. aeruginosa*).

P. aeruginosa often becomes resistant to antibiotics, which mean antibiotics don't work and people are left with a chronic infection which is difficult to treat. Having a chronic infection with *P. aeruginosa* means that you are more likely to be admitted to hospital, it may also increase your risk of more serious illness.

The purpose of this trial is to test whether an intravenous infusion (drip) containing a new drug called Gremubamab can reduce the amount of infection with *P. aeruginosa*. We'll also assess whether people with bronchiectasis can take this drug safely, and whether it reduces the number of bronchiectasis exacerbations and improves quality of life.

We will compare people who have been given the Gremubamab with people who have been given a placebo infusion, which is an inactive substance which looks the same as the Gremubamab.

What is involved?

Participation in the trial is entirely voluntary and you may withdraw at any time.

For the trial you will be asked to attend the hospital 8 times over a 6-month period. Each visit will take between 2 and 5 hours. Taxi transport can be arranged, or travel expenses reimbursed.

At each visit you will be seen by a Researcher. During these visits the Researcher will do a simple health check, monitor your symptoms, and assess your lung function and oxygen level. You will have some blood samples and sputum samples collected. You will also be asked to complete questionnaires.

You will be given either 3 Gremubamab or placebo infusions, 1 per month for 3 months. The other visits will assess how you are getting on.

You will not be able to choose whether you take the active Gremubamab or the inactive placebo. This will be decided randomly and neither you, nor your medical team will know what you are taking.

What are the possible benefits of taking part?

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

What are the possible disadvantages and risks of taking part?

There is an extremely small risk of severe allergic reaction. We will reduce the risk of you having an allergic reaction by giving you an antihistamine before your medication starts and giving the infusion slowly. You'll be monitored during all infusions of trial medication.

Who has reviewed the study?

The East of Scotland Research Ethics Service has examined this study and has raised no objections from the point of view of medical ethics.