The VITAL BE trial

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

Returning the enclosed REPLY SLIP in the SAE

Or

Call Researcher:
Najwa Soussi
0207 352 8121 x84974

Or

E-mail: n.soussi@rbht.nhs.uk

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

Your local Investigator for the trial is:

Principal Investigator:

Dr Michael Loebinger

Royal Brompton Hospital
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London
SW3 6HP

0207 351 8337

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The VitalBE trial

A Study of the Safety, Tolerability and Efficacy of 2 doses of Cayston (Aztreonam Lysine) compared to placebo in patients with bronchiectasis

IRAS Ref number: 252929

Royal Brompton & Harefield NHS
NHS Foundation Trust

VitalBE

Value of inhaled treatment with aztreonam lysine in bronchiectasis

Research to test a new treatment for bronchiectasis

Do you have bronchiectasis?

Have you had recent exacerbations?

You may be able to take part in a research trial

University of Dundee
NHS Tayside
tctu

What is the study about ?

Patients with bronchiectasis often suffer from coughing, sputum production and have chest infections that are difficult to treat.

We are carrying out a research trial to test whether a new treatment for bronchiectasis is effective. The treatment is to inhale a drug called Aztreonam using a nebuliser. This treatment is currently used to treat other similar lung diseases.

To test whether the treatment works we will compare the symptoms of people taking the Aztreonam treatnment with the symptoms of people taking a placebo, which is an inactive substance that looks the same as the active Aztreonam nebuliser. People taking part in the research will not be able to choose whether they take the active Aztreonam or the inactive placebo. This will be decided randomly and nether the person taking part, nor their medical team will know what they are taking.

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 Royal Brompton Hospital 6 times over a 13 month period. Each visit will take approximately 2 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 nose swabs taken and will be asked to produce a sputum sample. You will also be asked to complete 3 questionnaires about how you have been feeling.

You will be shown how to take your trial nebuliser and will then be asked to take it 2 or 3 times every day for a month when you will come back for a check up. The following month you will take no medicine, and the month after that you will take your medicine again. You will continue taking the nebuliser one month on, one month off for one year.

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

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.

Will my taking part in the study be kept confidential?

All your details will remain strictly confidential and will be stored in keeping with the UK Data Protection Act 2018.