

[Address]
[Date]

Dear [PARTICIPANT NAME]

VITAL BE trial

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

Patients who have bronchiectasis often suffer from chest infections that can be difficult to treat.

We are running a trial that will test a new way of treating bronchiectasis and we would like to invite you to consider taking part.

We will ask participants to inhale Cayston, an antibiotic nebuliser that is currently used to treat other lung diseases. To test whether this treatment is effective we will treat some participants with Cayston and some participants with a non-active placebo that looks the same as Cayston and then compare their bronchiectasis symptoms. Participants will not be able to choose whether they receive the active Cayston nebuliser or the in-active placebo nebuliser. This will be decided randomly, by computer, and neither the participants nor the clinical staff will know what the participant is taking.

For the trial you will be asked to attend Royal Derby Hospital for 6 visits over 12 months. Each visit will take approximately 1-2 hours. We will try to arrange these visits to coincide with your other routine hospital visits. Taxi transport can be arranged or travel expenses reimbursed.

I have enclosed a leaflet describing the trial in more detail and would be grateful if you would take the time to read it and consider taking part. If you are interested in taking part or would like to ask further questions please contact the trial team using the details below.



Call on 01332 789664



Return the attached REPLY SLIP in the SAE



E-mail melanie.hayman@nhs.net

Your participation is completely voluntary.

With kind regards,

Dr Tom Bewick

REPLY SLIP

Please complete the details below and return in the enclosed envelope.

Initials

I am interested in taking part in the VITAL BE Trial and I agree to be contacted by a member of the research team.

I agree to a member of the trial team looking at my medical records to confirm if I am likely to be suitable for the trial

Any identifiable information you provide here will be held securely by [SITE] in accordance with the UK Data Protection Act 2018. This information will only be used by your local trial team.

Name:

Address:

Telephone No:

Mobile No:

E-Mail Address:

Preferred method of contact:

Date:

Thank you for interest in the VITAL BE Trial