Value of inhaled treatment with aztreonam lysine in bronchiectasis

GP HEADED PAPER

[Address]
[Date]

Dear [PATIENT NAME]

VITAL BE trial
A Study of the Safety, Tolerability and Efficacy 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 working with [LOCAL PI] at [LOCAL HOSPITAL] on a research study that will test a new way of treating bronchiectasis and we would like you to consider taking part.

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

For the study you will be asked to attend [Local hospital] for 4 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. In addition, there will be 2 follow up phone visits. For hospital visits taxi transport can be arranged, or travel expenses reimbursed.

I have enclosed a leaflet describing the study 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 study team using the details below.

☎ Call on [local research team telephone number]

Return the attached REPLY SLIP in the SAE

E-mail [local research team e-mail address]

Your participation is completely voluntary.

With kind regards,

[GP]

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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 study team looking at my medical records to confirm if I am likely to be suitable for the study	

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