



Value of inhaled treatment with aztreonam lysine in bronchiectasis

Participant name:

Hospital ID/CHI:

Date of Birth:

Value of inhaled treatment with Aztreonam lysine in bronchiectasis- VITAL- BE

Sponsor University of Dundee-NHS Tayside
 Chief Investigator Professor James Chalmers
 IRAS number 252929

Principal Investigator

Contact number

Contact email

Visit 2 – Baseline/randomisation

Date of visit:

The above participant has agree to take part in the VitalBE clinical trial and has attended for their visit.

Please tick to indicate the following has been completed:

Confirmed participant’s identity

Participant has verbally given their consent to continue in the trial

Visit has been carried out as per protocol

Vital signs

Please enter the results of the following assessments:

Weight kg

Blood pressure mmHg Pulse bpm

Oxygen saturation (room air) % Tympanic temperature C

Pregnancy test

Is the participant a woman of child bearing potential? yes no

If female but not of child bearing potential how has this been confirmed?

Post-menopausal Date of last period

Permanent sterilisation

If female and of childbearing potential:

Has the participant agreed to either abstain from sexual activity or use a form of a medically approved birth control method?

Result of pregnancy test: negative positive

Randomisation

The eligibility check must be signed and dated by the doctor completing the check **before randomisation.**

Confirm participant has been randomised as per protocol

Trial medication

Tick to confirm:

Participant was given first dose of trial medication at visit

Change in FEV₁ from pre-dosing was less than 15%

Participant received training in the use of the nebuliser

Participant has been given training in the administration of the trial medication

Participant has been given trial medication, nebuliser and handset

Participant has been given Preparation of Trial Medication leaflet

Spirometry

What method of bronchodilation was used?

nebulised salbutamol Dose mg

inhaled salbutamol Dose mcg Number of puffs

Participant name:

Hospital ID/CHI:

Date of Birth:

Results of spirometry must be documented in notes.

Research blood sample obtained?	Yes	No
Spontaneous sputum sample obtained?	Yes	No
Is St George's Respiratory Questionnaire being completed?	Yes	No
Is Quality of Life Bronchiectasis Questionnaire being completed?	Yes	No
Is Bronchiectasis Health Questionnaire being completed?	Yes	No

The following must have source data documented in the medical notes. If not documented elsewhere these should be written in the notes.

- Changes to concomitant medications since last visit
- Any adverse events since last visit
- Any pulmonary exacerbations since last visit
- Any other notable findings and actions taken
- Eligibility criteria

The following should be filed in the participant's medical notes:

- Copy of GP letter

If the participant was withdrawn from the trial at this visit state reason:

--

Signature:

Name:

Job title:

Date:
