VitalBE

Value of inhaled treatment with aztreonam lysine in bronchiectasis

Discontinuation of Trial Medication
Withdrawal from Trial
Completion of Trial

Discontinuation of trial medication

Trial medication will be discontinued in the following circumstances:

- Pregnancy (a pregnancy notification form must be completed)
- Persistent adverse effects such as bronchospasm which are determined to be severe, persistent, treatment related and not responsive to treatment
- Inability to use the prescribed inhaled therapy
- Withdrawal from the trial will occur if there is a >15% reduction in FEV1 following initial drug administration that does not respond to bronchodilator treatment. Lung function changes at other time points in the trial would not be an indication for discontinuation of trial treatment unless meeting the above criteria of being associated with severe and persistent symptoms which are treatment related and cannot be managed by the site
- If an allergic reaction to trial drug occurs the trial drug will be stopped, and treatment will be initiated as appropriate. The occurrence of rash may be indicative of an allergic reaction to aztreonam

Discontinuation of trial medication – continuation of trial visits

- If a participant has been randomised and given one or more dose of IMP, they will be asked to complete trial visits as per the protocol, to allow for an intention to treat analysis. However participants are free to refuse to do so
- The Investigator may discontinue a participant's trial medication at any time, if it is in the best interest of the participant and treatment continuation would be detrimental to the participant's wellbeing
- The Investigator will make a clinical judgment as to whether or not an adverse event (AE) is of sufficient severity to require discontinuation of a participant's trial medication
- A participant may also voluntarily discontinue trial medication due to what they perceive as an intolerable AE
- If a participant discontinues trial medication but remains on the study, a Discontinuation of Trial Medication Form should be completed on the eCRF (Repeating Data Form)
- Record on TRuST that participant has Discontinued Study Drugs

Withdrawal from trial – stops all trial activity

- Participants are free to withdraw at any time and are not obliged to give reason(s)
- Discuss with the participant the value to the trial of discontinuing trial medication but continuing with trial follow up rather than withdrawing completely
- Make a reasonable effort to ascertain the reason(s), both for those who express their right to withdraw and for those lost to follow up, while fully respecting the individual's rights
- The participant should be offered an end-of-trial assessment
- If a participant withdraws and does not remain on the study, the Completion of Trial/Early Withdrawal visit should be completed on the eCRF

Completion of Trial

- Once a participant has completed all trial visits, the Completion of Trial/Early Withdrawal Visit must be completed