

ongoing trials - trial from other registries

An early-stage clinical trial to establish whether a new type of antibacterial (known as SASPject PT3.9) is a safe and effective way of treating people living with cystic fibrosis who have lung infections caused by the bacterium, *Pseudomonas aeruginosa*

Code: ISRCTN57413769 **Year:** 2026 **Date:**

Author:

Study design (if review, criteria of inclusion for studies)

Allocation: Randomized controlled trial; Masking: Blinded (masking used); Control: Placebo; Assignment: Part A SAD accelerated titration, adaptive, open Part B&C multiple dose, double blind, with placebo; Purpose: Treatment, Safety;

Participants

Inclusion criteria: 1. Males and females aged 18 years to 60 years at the time of providing consent; 2. Participants must be willing and able to comply with trial requirements; 3. A diagnosis of CF by sweat chloride or presence of applicable CFTR gene variant; 4. Ability to produce sputum adequately for all study visits; 5. *Pseudomonas aeruginosa* from sputum or throat swab in the last 12 months;

Interventions

Antibacterial therapy (SASPject PT3.9). Part A SAD (Phase 1b):Single ascending dose (SAD) study with 4 sequential dose levels (3E+08 pfu/dose, 3E+10 pfu/dose, 3E+12 pfu/dose and 3E+13 pfu/dose), optimised to have fewer participants at lower, sub-therapeutic, dose levels and increased participant numbers (N) at the 3rd and 4th dose level (with contingency to add participants to each dose cohort, should any dose limiting toxicity be observed). The route of administration will be IV, and all participants will receive the IMP at various concentrations, with no placebo used for this part of the study. Part B MAD (Phase 1b):This will consist of a multiple ascending dose (MAD) cohort (with the dose level tested in a traditional randomisation and observer/placebo blinding, 6 active, 2 placebo cohort design), utilizing the maximum tolerated dose established during the Part A SAD study. Dosing will be twice daily for three days, making 6 doses in total. The route of administration will be IV, and participants will receive the IMP at a fixed concentration or the placebo, depending on random assignment to a group. Part C MAD Extension (Phase 2a):This is an optional extension arm allowing for the optimised dose, determined by the Part B MAD and agreed by the Dose Escalation Committee, to be investigated in a larger cohort (up to 24 participants, 18 active, 6 placebo) in a double-blind and placebo-controlled design. The route of administration will be IV and participants will receive either the IMP or placebo twice daily for three days.

Outcome measures

Adverse events (AEs) and dose-limiting toxicities (DLTs) during the 60-day follow-up period, reviewed on days 1, 2, 5, 8, 11, 15, 30, 60 post treatment part A, plus days 3 and 4 for parts B&C.

<https://www.isrctn.com/ISRCTN57413769>

Keywords

Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Infection; Inhalation OR nebulised; Oral; pharmacological_intervention; *Pseudomonas aeruginosa*; *Pseudomonas*; Respiratory Tract Diseases; Respiratory Tract Infections; other anti-bacterial agents; SASPject PT3.9;