

A Study to Investigate the Safety, Tolerability, and Pharmacokinetics of Inhaled CHF6333 After Single Doses in Healthy Volunteers and After Single and Repeated Doses in Subjects With Bronchiectasis

NCT06166056

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Chiesi Farmaceutici S.p.A.
Enrollment	45 participants

Key Eligibility Criteria

Inclusion (23)

- Signed and dated informed consent obtained prior to any study-related procedure;
- Healthy male or female subject ≥ 18 and ≤ 60 years of age at screening;
- Ability to understand the study procedures and the risks involved, and to be trained to use inhalers correctly and to generate sufficient peak inspiratory flow (PIF) (at least 40 L/min) using the In-Check Dial set as per "GenuAir" inhaler resistance, at screening;
- Body mass index (BMI) ≥ 18 and ≤ 35 kg/m² at screening;
- Non-smokers or ex-smokers who smoked ≤ 5 pack-years and stopped smoking ≥ 1 year prior to screening;
- ... and 18 more (see full listing online)

Exclusion (45)

- Participation in another clinical study where investigational drug was received and the last investigations were performed less than 3 months prior to randomisation;
- Clinically relevant and uncontrolled respiratory, cardiac, hepatic, gastrointestinal, renal, endocrine, hematologic, metabolic, neurological, or psychiatric disorders that may interfere with successful completion of this protocol, according to the investigator's judgment;
- Clinically relevant abnormal laboratory values at screening suggesting an unknown disease and requiring further clinical investigation or which may impact the safety of the subject or the evaluation of the results of the study, according to the investigator's judgment;
- History of respiratory diseases;
- Positive human immunodeficiency virus (HIV) 1 or HIV2 serology results at screening;
- ... and 40 more (see full listing online)

Locations (9 total)

Royal Papworth Hospital NHS Foundation Trust, Cambridge Centre for Lung Infection, Cambridge, United Kingdom
Tayside Medical Science Centre, Ninewells Hospital & Medical School, Dundee, United Kingdom
NHS Lothian, Edinburgh, United Kingdom
... and 6 more locations

<https://clinicaltrials.gov/study/NCT06166056>

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