

ongoing trials - trial from other registries

# Study to Assess Amphotericin B Cystetic for Inhalation (ABCI) Doses in Healthy Volunteers & People With Cystic Fibrosis - Phase 1|Phase 2 - Recruiting

**Code:** NCT05802264    **Year:** 2023    **Date:**

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

Controlled: No.1 Randomised: No.2 Open: Yes.3 Single blind: No.4 Double blind: No.5 Parallel group: No.6 Cross over: No

## Participants

Principal inclusion criteria: 1.Subjects From Study VX16-809-122 Part B (Study 122) - Completed the 24-week Treatment Period and the Safety Followup Visit in Study 122B 2.Subjects Not From Study 122 - Subjects will be 1 to less than 2 years of age - Homozygous for the F508del mutation (F/F)

## Interventions

Long-term lumacaftor/ivacaftor (LUM/IVA) treatment

## Outcome measures

Primary end point(s): Safety and tolerability as assessed by the number of adverse events (AEs) and serious adverse events (SAEs)

<https://ClinicalTrials.gov/show/NCT05802264>

## Keywords

Child; Aminophenols; CFTR Modulators; Genetic Predisposition to Disease; Orkambi; pharmacological\_intervention; VX-770; ivacaftor; lumacaftor; VX-809;