

A Double-Blind, Active-Controlled, Multiple-Ascending Dose Study of Aerosolized RSP-1502 in Subjects With CF and Chronic PA Lung Infection

NCT06016088

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| Status | RECRUITING |
| Phase | Phase 1, Phase 2 |
| Sponsor | Respirion Pharmaceuticals Pty Ltd |
| Enrollment | 72 participants |

Key Eligibility Criteria

Inclusion (11)

- Males or females aged ≥ 18 years of age for cohorts 1-4; males or females ≥ 12 years of age for cohort 5.
 - Diagnosis of CF based on the following: historical positive sweat chloride value ≥ 60 mEq/L, and/or genotype with two identifiable mutations consistent with CF, accompanied by one or more clinical features consistent with the CF phenotype.
 - History of *P. aeruginosa*-positive sputum cultures or throat swabs with at least 50% positive in the 2 years preceding screening.
 - *P. aeruginosa*-positive sputum culture at screening.
 - Forced expiratory volume in 1 second (FEV1) ≥ 30 and $\geq 120\%$ predicted per Global Lung Function Initiative (GLI) equation, pre- or post-bronchodilator.
- ... and 6 more (see full listing online)

Exclusion (20)

- A history of previous allergy or sensitivity to components of RSP 1502.
 - A history of intolerance to inhaled tobramycin (TOBI®, BETHKIS®, TOBI® Podhaler®, tobramycin inhalation solution).
 - eGFR < 40 mL/min, or serum total bilirubin $> 2X$ or serum transaminases $> 3X$ the upper limit of normal range at screening.
 - Currently taking other medications with known nephrotoxic, neurotoxic, or ototoxic potential (subjects receiving inhaled tobramycin in conjunction with low dose azithromycin prior to study participation without evidence of ototoxicity may continue taking low dose azithromycin during the study).
 - Currently taking ethacrynic acid, furosemide, urea, or intravenous mannitol.
- ... and 15 more (see full listing online)

Locations (22 total)

Tucson Cystic Fibrosis Center, Tucson, Arizona, United States
Center for Cystic Fibrosis at Keck Medical Center of USC, Los Angeles, California, United States
Stanford University Medical Center, Palo Alto, California, United States
... and 19 more locations

<https://clinicaltrials.gov/study/NCT06016088>

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