

Standardizing Treatments for Pulmonary Exacerbations - Aminoglycoside Study

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: 6 years and over

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

- All genders $\geq$ 6 years of age at Visit 1
- Documentation of a CF diagnosis
- Clinician intent to treat index CF PEx with a planned 14-day course of IV antimicrobials
- At least one documented Pa positive culture within two years prior to Visit 1

Exclusion Criteria:

- Participant is not pregnant
- No known renal impairment or history of solid organ transplantation
- No IV antimicrobial treatment, ICU admission, pneumothorax, or hemoptysis within 6 weeks prior to Visit 1
- No use of investigational therapies, new CF transmembrane conductance regulator (CFTR) modulators, or treatment for Nontuberculous mycobacteria (NTM) within 4 weeks prior to Visit 1
- No history of hypersensitivity, vestibular, or auditory toxicity with aminoglycosides
- No more than one day of IV aminoglycosides administered for the current PEx treatment prior to Visit 1

Conditions & Interventions

Interventions:

DRUG: Beta-lactam antibiotic, DRUG: Aminoglycoside

Conditions:

Cystic Fibrosis, Cystic Fibrosis Pulmonary Exacerbation

Keywords:

Cystic Fibrosis, CF, Cystic Fibrosis Pulmonary Exacerbation, aminoglycoside, beta-lactam, β -lactam, STOP, STOP360

More Information

Description:

The purpose of this study is to look at pulmonary exacerbations in people with cystic fibrosis (CF) that need to be treated with antibiotics given through a tube inserted into a vein (intravenous or IV). A pulmonary exacerbation is a worsening of respiratory symptoms in people with CF that needs medical intervention. Both doctors and CF patients are trying to understand the best way to treat pulmonary exacerbations. This study is trying to answer the following questions about treating a pulmonary exacerbation: * Do participants have the same improvement in lung function and symptoms if they are treated with one type of antibiotic (called beta-lactams or β -lactams) versus taking two different types of antibiotics (tobramycin and β -lactams)? * Is taking one type of antibiotic just as good as taking two types?

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Principal Investigator ID:

Phase: PHASE4

IRB Number:

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