Dorzagliatin in Pancreatic Insufficient Cystic Fibrosis

NCT06995651

Status	RECRUITING
Phase	Phase 1
Sponsor	University of Pennsylvania
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (9)

- Provision of signed and dated informed consent form.
- Stated willingness to comply with all study procedures and availability for the duration of the study.
- Male or female, aged e18 years on date of consent.
- Confirmed diagnosis of CF, defined by positive sweat test or CFTR mutation analysis according to CFF diagnostic criteria.
- Pancreatic insufficiency defined by clinical requirement for pancreatic enzyme replacement.

... and 4 more (see full listing online)

Exclusion (14)

- Established diagnosis of non-CF diabetes (e.g. type 1 diabetes).
- Pregnancy or lactation; a negative urine pregnancy test will be required at enrollment.
- Pulmonary exacerbation requiring IV antibiotics or systemic glucocorticoids within 4 weeks prior to randomization.
- Treatment with either CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin, indinavir, ritonavir, saquinavir, telithromycin, boceprevir, nelfinavir, telaprevir, conivaptan, nefazodone, etc.) or inducers (e.g. phenobarbital, other barbiturates, carbamazepine, phenytoin, rifampicin, dexamethasone, etc.).
- Use of herbal remedies, including St. John's Wort within 14 days prior to dosing.

... and 9 more (see full listing online)

Locations (2 total)

Hospital of University of Pennsylvania, Philadelphia, Pennsylvania, United States
University of Pennsylvania Center for Human Phenomic Science (CHPS), Philadelphia, Pennsylvania, United States