

Pancreatic Enzyme Replacement Therapy for Acute Pancreatitis-Associated Exocrine Pancreatic Insufficiency

NCT06477159

Status	RECRUITING
Phase	Phase 4
Sponsor	Ohio State University
Enrollment	60 participants

Key Eligibility Criteria

Inclusion (13)

- Adult patients of age 18 or older, able to provide informed consent and follow all study procedures.
- Stable outpatient up to 12 months following an acute pancreatitis episode and has EPI based on an FE-1 < 200 $\mu\text{g/g}$ stool obtained within 3 months prior to baseline assessment (Visit 2).
- Score of equal or greater 0.6 on the EPI symptom tracker at baseline Visit 2.
- Must be off PERT (including prescription and non-prescription enzymes) for 7 days prior to baseline Visit 2.
- Must have fully completed the terminal intervention for necrotizing pancreatitis (surgical or endoscopic necrosectomy or percutaneous drainage).

... and 8 more (see full listing online)

Exclusion (10)

- Acute pancreatitis episode due to a pancreatic cystic neoplasm, trauma, or surgery. Post-ERCP acute pancreatitis patients can be enrolled.
- History of definite chronic pancreatitis defined by APA Chronic Pancreatitis Guideline.1
- Pancreas malignancy or other active malignancies requiring systemic treatment; treated basal cell carcinoma, and treated in-situ cervical cancer can be included.
- Enteropathies, and gastroenteritis that may affect FE-1 levels, e.g., Inflammatory bowel disease, Celiac Disease, viral-, bacterial-, fungal-, or parasitic gastroenteritis.
- Gastroparesis.

... and 5 more (see full listing online)

Locations (5 total)

University of Southern California, Los Angeles, California, United States
University of Illinois Chicago, Chicago, Illinois, United States
New York University Langone Medical Center, New York, New York, United States
... and 2 more locations