

STTEPP: Safety, Tolerability and Dose Limiting Toxicity of Lacosamide in Patients With Painful Chronic Pancreatitis

NCT05603702

Status	RECRUITING
Phase	Phase 1
Sponsor	Indiana University
Enrollment	24 participants

Key Eligibility Criteria

Inclusion (10)

- written informed consent and HIPAA authorization for release of personal health information;
- e 18years old at the time of informed consent;
- suspected (YELLOW 2 or 3) or definite diagnosis of CP, as per CPDPC PROCEED study definition with ongoing symptoms of abdominal pain;
- patients must be maintained on an opioid (except methadone or suboxone) for 4 weeks prior to enrollment for treatment of abdominal pain related to pancreatitis;
- ongoing symptoms of abdominal pain even with opioid use (VAS and BPI average score e4, at enrollment);
- ... and 5 more (see full listing online)

Exclusion (14)

- subjects with indeterminate CP (YELLOW 1) as per PROCEED criteria;
- treatment with any investigational agent within 30 days prior to registration, or concurrent participation in a clinical trial which involves another investigational agent;
- rapidly escalating pain that requires parenteral (intravenous or intramuscular) opioid therapy within 30 days of enrollment;
- known hypersensitivity/allergic reaction to lacosamide, carbamazepine or oxcarbazepine;
- pregnant or breastfeeding;
- ... and 9 more (see full listing online)

Locations (5 total)

Stanford University, Stanford, California, United States
Indiana University, Indianapolis, Indiana, United States
Mayo Clinic, Rochester, Minnesota, United States
... and 2 more locations