

A 26-Wk Study to Assess Safety & Efficacy of Tenapanor for T/t of Chronic Idiopathic Constipation in Adults

NCT07382167

Status	RECRUITING
Phase	Phase 3
Sponsor	Ardelyx
Enrollment	692 participants

Key Eligibility Criteria

Inclusion (8)

- Patients e18 to d80 years old at the Screening visit (Visit 1).
- Meet the Rome IV Diagnostic Criteria for functional constipation.
- Females of non-childbearing potential, or agree to the use of an acceptable means of contraception for up to 30 days following the last dose of study medication.
- Males must agree to use an appropriate method of barrier contraception or have documented surgical sterilization.
- Meets the entry criteria assessed during the Screening period.

... and 3 more (see full listing online)

Exclusion (19)

- Loose or watery stool in the absence of any medication that is known to affect stool consistency for >25% of bowel movements (BMs) during the 3 months prior to the Screening visit
- Fecal impaction within 6 months prior to the Screening visit
- Unexplained and clinically significant alarm symptoms.
- Functional diarrhea as defined by Rome IV criteria
- IBS with constipation (IBS-C), IBS with diarrhea (IBS-D), mixed IBS (IBS-M), or unsubtyped IBS as defined by Rome IV criteria

... and 14 more (see full listing online)

Locations (79 total)

Arizona Liver Health - Chandler, Chandler, Arizona, United States

Elite Clinical Studies, Phoenix, Arizona, United States

Arkansas Gastroenterology - North Little Rock, North Little Rock, Arkansas, United States

... and 76 more locations