

A Study to Learn About the Safety of Vedolizumab and How Well it Works in Children and Teenagers With Active Chronic Pouchitis

NCT06443502

Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (6)

- The participant weighs ≥ 10 kg at the time of screening and first dose.
- Has active chronic pouchitis, defined by a mPDAI score ≥ 5 assessed using the 3-day average of participant-reported clinical symptoms prior to the screening endoscopy (that is [ie] video pouchoscopy with biopsy) or bowel preparation for the endoscopy and a minimum mPDAI endoscopic subscore of 2 (outside the staple or suture line) and either:
- ≥ 1 previous episodes of pouchitis within 1 year before the screening visit, with symptoms lasting for at least a total of 4 weeks, treated with ≥ 2 weeks of antibiotic or other prescription therapy (ie, other antibiotics, probiotics, immunomodulators, or anti-tumor necrosis factor [TNFs]) within 1 year before screening). Or
- Have had an inadequate response with, or lost response to, or be intolerant to antibiotic therapy (ie, requiring maintenance antibiotic therapy taken for ≥ 4 weeks immediately before the baseline endoscopy visit or not able to receive or continue antibiotic treatment due to intolerance or other contraindication).
- The participant is aged 2 to 17 years, inclusive, at the time of screening and first dose.

... and 1 more (see full listing online)

Exclusion (23)

- Has symptoms believed to be predominantly due to irritable pouch syndrome.
- Has isolated cuffitis.
- Is found to have dysplasia at the screening endoscopy.
- Has mechanical complications of the pouch (for example [e.g.] pouch stricture or pouch fistula).
- Currently requires or has a planned surgical intervention during the study.

... and 18 more (see full listing online)

Locations (14 total)

UZ Leuven, Leuven, Vlaams-Brabant, Belgium
Children's Hospital Zagreb, Zagreb, Croatia
Fakultni nemocnice v Motole, Pediatricka klinika 2, Prague, Czechia
... and 11 more locations