

Gelsectan® in the Treatment of Patients With Diarrhoea-predominant Irritable Bowel Syndrome

NCT06681012

Status	RECRUITING
Phase	Not Applicable
Sponsor	Devintec Sagl
Enrollment	330 participants

Key Eligibility Criteria

Inclusion (13)

- Male or female, age e18 years and d 65 years.
- Positive diagnosis of IBS, according to Rome IV diagnostic criteria, namely recurrent abdominal pain, on average, at least 1 day/week in the last 3 months associated with two or more of the following criteria:
 - related to defecation
 - associated with a change in frequency stool
 - associated with a change in form (appearance) of stoolThe above criteria must be fulfilled for the last 3 months with symptom onset at least 6 months before diagnosis.
- ... and 8 more (see full listing online)

Exclusion (16)

- Presence of any relevant organic, systemic or metabolic disease (particularly significant history of cardiovascular, renal, neurological, endocrine, metabolic or hepatic disease) that would preclude participation in this study in the opinion of the Investigator, or abnormal laboratory values that will be deemed clinically significant on the basis of predefined values.
- Known perforation and/or gastrointestinal obstruction.
- Ascertained organic gastrointestinal diseases, including celiac disease, bile acid malabsorption or inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticular disease, infectious colitis, ischemic colitis, microscopic colitis).
- Presence of other intestinal motility disorders, such as biliary dyskinesia, gastroparesis, intestinal pseudo-obstruction, and narcotic bowel syndrome.
- Previous major abdominal surgery (uncomplicated appendectomy, cholecystectomy, polypectomy, inguinal hernia surgery, or caesarean section are allowed unless within six months prior to screening).
- ... and 11 more (see full listing online)

Locations (12 total)

University Hospitals Leuven (UZ Leuven), Leuven, Belgium
Hôpital Avicenne, Bobigny, France
CHU de Rouen, Rouen, France
... and 9 more locations

<https://clinicaltrials.gov/study/NCT06681012>

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