

MEIN/06/OB-20/80/001

A Dose-Ranging Study of Otilonium Bromide in Patients with Irritable Bowel Syndrome

This study has completed the enrolment of patients

Sponsor: A. Menarini Industrie Farmaceutiche Riunite

Intervention: Otilonium bromide, tablets 20, 40, 80 mg t.i.d or Placebo for a treatment period of 4 weeks

Indication: Irritable Bowel Syndrome

This study is designed to demonstrate a dose-response relationship of otilonium bromide in treatment-sensitive functional and/or clinical efficacy variables of IBS

Study type & design: Double-blind, placebo-controlled, randomized dose-ranging study in 4 parallel groups of 24 (16 female and 8 male) patients each

Main criteria for inclusion:

Patients with IBS diagnosed according to the Rome II Criteria;

Age ≥ 18 and ≤ 65 years

Patients who have at least a 6-month history of IBS, with at least moderate abdominal pain or discomfort occurring on at least 4 days in each of the 4 weeks prior to the study

Accurate anamnesis to exclude in particular the lactase deficiency syndrome (requiring H₂-breath tests, when clinically strongly suspected), bowel inflammatory disease, diets or drugs that may cause gastrointestinal symptoms and alvus disturbances

Main criteria for exclusion:

Patients whose condition cannot be definitely diagnosed as IBS

Previous severe abdominal surgery

Other concomitant diseases which could have a relevant impact on study results

Any malignancy

Any concomitant treatment that could affect gastrointestinal motility and function (calcium channel blockers, anticholinergics, prostaglandin drugs, antiacids, prokinetics, meconics, laxatives, antidiarrheals, antidepressives, analgesics, tranquillizers), and which cannot be stopped participation in another clinical study within 2 months prior to enrolment