

MeFi/04/OBR-IBS/001

Otilonium Bromide in Irritable bowel Syndrome (OBIS)
Double blind, randomized, parallel group, placebo-controlled study to evaluate the effect of otilonium bromide on abdominal pain and quality of life in patients with irritable bowel syndrome

This study is currently recruiting patients

Sponsor: A.Menarini Farmaceutica Internazionale srl

Intervention: Otilonium bromide 40 mg tablets t.i.d. before meals (120 mg OB/day), or matching placebo

Condition: Irritable bowel syndrome

Study type & design: Randomized, double-blind, parallel group, placebo-controlled study.

Main criteria for inclusion:

Patients meeting the following criteria will be included:

- Male or female patients aged over 18 years
 - Positive diagnosis for IBS according to the following symptom-based criteria (Rome II): 12 weeks or more, which need not to be consecutive, in the last 12 months of abdominal pain/discomfort that has two of the following three features:
 - (a) Relieved by defecation
 - (b) Associated with a change in frequency of stool
 - (c) Associated with a change in consistency of stool
- At least 2 episodes of abdominal pain for each week during the two weeks of run-in (at visit 2).

Main criteria for exclusion

- Pregnant and breast-feeding women

- Simultaneous participation in another clinical trial
- Inability to maintain the conditions of the trial
- Severe psychiatric disorders
- Severe neurological disorders
- Severe heart failure, severe ischemic heart disease and severe hypertension
- Lactose intolerance
- Any clinical condition capable of causing gastrointestinal malabsorption
- Previous intestinal surgery except appendectomy
- History of organic gastro-intestinal disease, (e.g. inflammatory bowel disease, cancer, ectopic endometriosis)
- Parasitosis infection
- Bowel obstruction
- History of the following diseases in the previous 4 months:
 - Clinically symptomatic severe anaemia
 - Cholestasis
 - Diabetes mellitus requiring treatment with oral antidiabetics or insulin
 - Severe hepatic or renal functional abnormality according to investigator's opinion
- Any chronic use (> 2 weeks continuously) in the previous month of concomitant medication that may affect gastro-intestinal motility and function and that cannot be stopped during the trial such as: anticholinergics, prokinetics, laxatives, antidiarrhoeals, analgesics, NSAIDs, opiates, antidepressants, probiotics and drugs adjusting the microbial state. An antithrombotic treatment with low dose of aspirin is permitted.
- Clinically relevant abnormal values in the laboratory tests
- Glaucoma
- Prostatic hypertrophy
- Pyloric stenosis
- Hypersensitivity to any ingredient of the study products (otilonium bromide and/or excipients).