Perifere histamine 1 receptor blokkade in PDS

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON55611

Source
ToetsingOnline

Brief title
Peripheral histamine 1 receptor blockade in IBS

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Irritable bowel syndrome

Research involving
Human

Sponsors and support

Primary sponsor: UZ Leuven
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ebastine, Histamine 1 receptor, irritable bowel syndrome, visceral hypersensitivity

Outcome measures

Primary outcome

The primary endpoinst in this study is the effect of ebastine on abdominal pain

and global relief of symptoms in IBS patients

Secondary outcome

Secondary, we will assess the impact on the IBS stool consistency and frequency

and many other common complaints such as bloating, flatulence, urgency and

feeling of incomplete evacuation. Finally, we will determine the effect of the

treatment on the quality of life.

Study description

Background summary

It is estimated that in the Western world, 1 in 5 people suffer from irritable bowel syndrome (IBS; synonyms: spastic colon and IBS). Typical complaints of IBS are abdominal pain or discomfort and a changing defecation pattern. These complaints occur without a clear organic cause. The treatment of IBS so far is rather disappointing. Today the treatment of IBS consists of advice, fiber preparations, agents that reduce the tone of the bowel or stimulate motility of the intestine ("antispasmodics" and "prokinetics"), low-dose antidepressants and painkillers. Recently, it was demonstrated that the gut of IBS patients showed a slight increase in inflammation. This inflammation is too low to speak of an inflammatory disease (such as Crohn's disease or ulcerative colitis) but this inflammation could be the cause of the development of symptoms. Inflammatory cells can secrete substances that may cause increased sensitivity of the intestine, which occures in many IBS patients,. One of the substances which can be secreted by inflammatory cells, is histamine. Therefore we now investigate a drug that counteracts the effects of histamine. The drug (Ebastine) is currently used in the treatment of allergic diseases.

Study objective

We want to examine the effect of the antihistamine Ebastine on abdominal pain and other symptoms associated with IBS and the quality of life. Through this research we would like to emphasize that this study primarily focuses on improvements of the symptoms associated with IBS.

Study design

The studydesign is multicentric, double-blind, randomized and placebo-controlled. It includes a two-week screening, followed by a treatment period followed by a 2 week follow-up period. Patients will be randomized 1:1 for a 12 weeks of treatment with 20mg 1dd ebastine or placebo (Figure see protocol). The patient has to fill out daily and weekly questionnaires about their symptom relief and quality of life. These questionnaires will serve as source documents in the study.

Intervention

12 weeks treatment with placebo or Ebastine

Study burden and risks

The risk for the subject is very small because the risk of side effects of Ebastine is very rare (1 in 10 000). For the patient, the load of the study is not that big. The patient must fill out questionnaires weekly and come to visit the doctor for 5 times.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Patients meet the ROME III criteria for IBS and is NOT diagnosed with the constipation dominant subform of IBS (IBS-C), 2. No identifiable organic explanation for the symptoms (including the execution of a test for lactose intolerance, celiac disease and giardia test), 3. Age 18-65 years, 4. Signed informed consent, 5. Symptoms during the two weeks of screening

Exclusion criteria

1. IBS constipation dominant, 2. Patient with history of:, Celiac disease, Known milk allergy, giardiasis, inflammatory bowel disease, active intestinal infection, chronic intestinal ischemia, chronic subobstruction, pseudo-obstruction, dumping syndrome, pancreatic insufficiency, hepatic impairment, renal function impairment, cardiovascular disease, extensive gastrectomy and/or bowel resection, active malignant disease, thyroiddysfunction, insulin dependent diabetes mellitus, psychiatric disorder, any clinical condition in which the researcher does not allow to terminate the study safely, 3. Pregnancy, breastfeeding, 4. Medication: Use of anti-allergica, antidepressants, and antipsychotics, 5. Patient uses drugs that reduce gastrointestinal motility and / or affect the visceral perception (anticholinergics, antispasmodics, 5-HT4 agonists, cholinomimetics, loperamide, laudanum, codeine, stimulant laxatives, macrogol, paraffin oil, anti-inflammatory agents) OR mediaction knwon to prolong QTc-interval (antifungals (ketoconazol) and macrolides (erytromycien, claritromycine))., 6. Complaints arise after abdominal surgery

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-12-2015
Enrollment:	120
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ebastine TEVA
Generic name:	Ebastine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	04-06-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	20-01-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-01-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-02-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-001199-39-NL

Register	ID
ClinicalTrials.gov	NCT01908465
CCMO	NL45773.018.13