The effect of H1 receptor antagonist on rectal sensitivity

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22721

Source
NTR

Brief title
N/A

Health condition

Iriitabel Bowel Syndrome (IBS)
Prikkelbaar Darm Syndroom (PDS)

Sponsors and support

Primary sponsor: Acadamic Medical Center Amsterdam
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Effect of Fexofenadine on rectal sensitivity in IBS patients

Secondary outcome

Improvement of abdominal symptoms and qualty of life in IBS patients

Study description

Background summary

Irritable Bowel disease is a functional bowel disorder with a high prevalence, caracterized by low respons on regular therapy and most of the time a poor quality of life. Previeus studies have shown that hypersensitivity of the rectum, measured by barostat, is one explanation of developping abdominal symptoms. This hypersensitivity is probably caused by the mastcell. A study with a mastcell stabilizator ketotifen reduced the rectal hypersensitivity and symptomsscore. However there was no change in mastcell activity seen, suggesting that the effect of ketotifen is due to H1 receptor antagonism. The aim of this study is to investigated if fexofenadine, a specific H1 receptor antagonist, will reduced rectal sensitivity and secondairy will lead to improvement of symptoms and quality of life.

IBS patients who will meet the Rome III Criteria will be randomized in a double blind placebo controlled trial with 8 weeks of treatment with 180-360 mg fexofenadine a day. Before and at the end of the treatment a barostat investigation will be performed for measuring the rectal sensititivity.

Study objective

Inhibition of the H1 receptor will lead to an improvement of rectal sensitivity, followed by less abdominal symptoms in patients with irritable bowel syndrome.

Study design

12 weeks trial. 2 weeks screening, 8 weeks of treatment and 2 weeks foolow up.

Intervention

During 8 weeks patients with IBS will recieved a treatment with Fexofenadine, an H1 receptor antagonist, or placebo.

The first 2 weeks 180 mg/day, then 6 weeks 360 mg/day. Before start and end of the study a barostat investigation will be performed for measuring the rectal sensitivity.

Contacts

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Eligibility criteria

Inclusion criteria

1. 18-65 years

2. Patients have to meet the Rome Criteria for IBS

Exclusion criteria

1. Severe comorbidity like DM, kidneydiseases, liverdiseases cardiovasculair diseases.

2. Major abdominal surgery in history.

3. Use of antihistaminica, hypnotics or sedative medication

4. Pregnancy or breastfeeding

5. Indepandancy of alcohol

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	60
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1274
NTR-old	NTR1320

Register	ID
Other	2008-003348-12 : fex1
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A