

Irritable Bowel Syndrome - Ketotifen.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23097

Source

NTR

Brief title

N/A

Intervention

Outcome measures

Primary outcome

The effect of the mastcell-stabilizer ketotifen on the rectal sensitivity in IBS.

Participants are treated with ketotifen twice daily 2-6 mg or placebo during eight weeks.

To assess the rectal sensitivity a barostat investigation is performed before and after the treatment-period.

Secondary outcome

The effect of the mastcell-stabilizer ketotifen on inflammation in rectal biopsy specimen and the effect of ketotifen on IBS-symptoms.

Study description

Background summary

Treatment: 2, 4 or 6 mg ketotifen BID or placebo for 2 months. Patients will undergo a barostat before and after treatment.

Prior to the barostats 6 rectal biopsies will be taken via a proctoscope.

Study objective

N/A

Study design

N/A

Intervention

2, 4 or 6 mg ketotifen BID or placebo for 2 months.

Contacts

Public

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Eligibility criteria

Inclusion criteria

Fulfilling Rome II criteria of IBS, 18-65 years of age, no other organic abnormalities explaining the complaints.

Exclusion criteria

Severe comorbidity, use of sedatives, hypnotics or antihistamines, pregnancy/lactation.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2005
Enrollment:	64
Type:	Actual

Ethics review

Positive opinion	
Date:	31-05-2005
Application type:	First submission

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	NL15
NTR-old	NTR39
Other	: N/A
ISRCTN	ISRCTN22504486

Study results

Summary results

N/A