Irritable Bowel Syndrome - Budesonide.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28758

Source
NTR

Brief title
N/A

Intervention

Outcome measures

Primary outcome

The effect of budesonide on the rectal sensitivity in IBS. Participants are treated with budesonide 3 dd 3 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 budesonide on inflammation in rectal biopsy specimen and the effect of budesonide on IBS-symptoms.

Study description

Background summary

Treatment: 3 mg Budesonide TID 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

Intervention

3 mg Budesonide TID or placebo for 2 months

Contacts

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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, pregnancy/lactation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-04-2005
Enrollment:	32
Type:	Anticipated

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	NL19
NTR-old	NTR40
Other	: N/A
ISRCTN	ISRCTN31751611

Study results

Summary results
N/A