

Irritable Bowel Syndrome: Budesonide

Submission date 04/08/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/08/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/06/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR40

Study information

Scientific Title

Budesonide as treatment for patients with irritable bowel syndrome

Study hypothesis

To evaluate budesonide as treatment for patients with irritable bowel syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local ethics committee.

Study design

Randomised, placebo controlled, parallel group, double blinded trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Condition

Irritable bowel syndrome (IBS)

Interventions

3 mg budesonide three times a day (TID) or placebo for two months. Patients will undergo a barostat before and after treatment. Prior to the barostats six rectal biopsies will be taken via a proctoscope.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Budesonide

Primary outcome measure

The effect of budesonide on the rectal sensitivity in IBS.

Secondary outcome measures

1. The effect of budesonide on inflammation in rectal biopsy specimen
2. The effect of budesonide on IBS-symptoms

Overall study start date

01/04/2005

Overall study end date

01/01/2006

Eligibility

Participant inclusion criteria

1. Fulfilling Rome II criteria of Irritable Bowel Syndrome (IBS)
2. 18 to 65 years of age
3. No other organic abnormalities explaining the complaints

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

32

Participant exclusion criteria

1. Severe comorbidity
2. Pregnancy/lactation

Recruitment start date

01/04/2005

Recruitment end date

01/01/2006

Locations

Countries of recruitment

Netherlands

Study participating centre
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Emma Kinderziekenhuis
Postbus 22660
Amsterdam
Netherlands
1105 AZ

Sponsor type
University/education

Website
<http://www.amc.uva.nl/>

ROR
<https://ror.org/03t4gr691>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration