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Irritable Bowel Syndrome: Budesonide

Submission date	Recruitment status	[ ] Prospectively registered
04/08/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/08/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/06/2008	Digestive System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 objectives
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

Health condition(s) or problem(s) studied
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

Completion date
01/01/2006

Eligibility

Key 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

Key exclusion criteria
1. Severe comorbidity
2. Pregnancy/lactation

Date of first enrolment
01/04/2005

Date of final enrolment
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