

Irritable Bowel Syndrome: Budesonide

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr G E E Boeckxstaens

Contact details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 566 7375
g.e.boeckxstaens@amc.uva.nl

Additional identifiers

Protocol serial number
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.

Primary study design

Interventional

Study design

Randomised, placebo controlled, parallel group, double blinded trial

Study type(s)

Treatment

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(s)

The effect of budesonide on the rectal sensitivity in IBS.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration