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# Irritable Bowel Syndrome: Budesonide

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

**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.

### Study design
Randomised, placebo controlled, parallel group, double blinded trial

### Primary study design
Interventional

### 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
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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