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Irritable Bowel Syndrome: Ketotifen

Submission date 04/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/08/2005	**Overall study status** Completed	
Last Edited 02/12/2010	**Condition category** Digestive System	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR39

Study information

Scientific Title

The effect of a mast cell-stabiliser on rectal sensitivity

Study objectives
To assess the effect of a mast cell-stabiliser on rectal sensitivity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from local ethics committee

Study design
Randomised, placebo controlled, parallel group 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
Patient will be randomised to receive either 2, 4 or 6 mg ketotifen twice a day (BID) 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)
Ketotifen

Primary outcome measure
The effect of the mast cell-stabiliser ketotifen on the rectal sensitivity in IBS.

Secondary outcome measures

1. The effect of the mast cell-stabiliser ketotifen on inflammation in rectal biopsy specimen
2. The effect of ketotifen on IBS-symptoms

Overall study start date
01/06/2005

Completion date
01/06/2006

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
64

Key exclusion criteria
1. Severe comorbidity
2. Use of sedatives, hypnotics or antihistamines
3. Pregnancy/lactation

Date of first enrolment
01/06/2005

Date of final enrolment
01/06/2006

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2010		Yes	No