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Irritable Bowel Syndrome: Ketotifen

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	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/12/2010	Digestive System	

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
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

Primary study design
Interventional

Study design
Randomised, placebo controlled, parallel group trial

Study type(s)
Treatment

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(s)
The effect of the mast cell-stabiliser ketotifen on the rectal sensitivity in IBS.

Key secondary outcome(s)
1. The effect of the mast cell-stabiliser ketotifen on inflammation in rectal biopsy specimen
2. The effect of ketotifen on IBS-symptoms

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

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. 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)

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

Study outputs

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