# Irritable Bowel Syndrome - Ketotifen.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON23097

**Source**
Nationaal Trial Register

**Brief title**
N/A

### Intervention

### Outcome measures

#### Primary outcome

The effect of the mastcell-stabilizer ketotifen on the rectal sensitivity in IBS.

Participants are treated with ketotifen twice daily 2-6 mg or placebo during eight weeks.

To assess the rectal sensitivity a barostat investigation is performed before and after the treatment-period.

#### Secondary outcome

The effect of the mastcell-stabilizer ketotifen on inflammation in rectal biopsy specimen and the effect of ketotifen on IBS-symptoms.

# Study description

### Background summary

Treatment: 2, 4 or 6 mg ketotifen BID or placebo for 2 months. Patients will undergo a barostat before and after treatment.

Prior to the barostats 6 rectal biopsies will be taken via a proctoscope.

### Study objective

N/A

### Study design

N/A

### Intervention

2, 4 or 6 mg ketotifen BID or placebo for 2 months.

# Contacts

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# Eligibility criteria

## Inclusion criteria

Fulfilling Rome II criteria of IBS, 18-65 years of age, no other organic abnormalities explaining the complaints.

## Exclusion criteria

Severe comorbidity, use of sedatives, hypnotics or antihistamines, pregnancy/lactation.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-06-2005 |
| Enrollment: | 64 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 31-05-2005 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL15 |
| NTR-old | NTR39 |
| Other | : N/A |
| ISRCTN | ISRCTN22504486 |

# Study results

**Summary results**
N/A