# Does the presence of a hiatal hernia affects the efficacy of the reflux inhibitor baclofen?

No registrations found.

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

## Summary

### ID

NL-OMON23260

**Source**
Nationaal Trial Register

**Brief title**
N/A

**Health condition**

Gastroesophageal reflux disease (GERD), hiatal hernia

### Sponsors and support

**Primary sponsor:** Academic Medical Center (AMC), Department of Gastroenterology and Hepatology
**Source(s) of monetary or material Support:** AstraZeneca R&D, Mölndal, Sweden

### Intervention

### Outcome measures

**Primary outcome**

- The number of reflux episodes (acid and non acid) measured over 24 hours

### Secondary outcome

- Total acid exposure time, the composition of the refluxate and the proximal extent of the refluxate

## Study description

### Background summary

The presence of a hiatal hernia may hamper the efficacy of anti-TLESR therapy in the treatment of gastroesophageal reflux disease (GERD) as other mechanisms for reflux to occur become more important. Therefore, a randomized, placebo controlled double blind crossover studywill be performed, whereby the effect of baclofen on the rate of reflux episodes will be evaluated in GERD patient with (¡Ý 3cm) and without hiatal hernia. Patients will undergo twice a combined ambulatory 24 hours impedance pH metry measurement while on PPI¡¯s and 3x20mg baclofen or placebo. Acid and non-acid reflux rate, acid exposure time and acid clearance will be analysed for both studydays and compared between both patientgroups.

### Study objective

The efficacy of reflux inhibitors, which block transient lower esophageal sphincter relaxations (TLESRs), to reduce acid and non-acid exposure may be hampered in the presence of a hiatal hernia, as other mechanisms of reflux become more important.

### Study design

The ambulatory impedance/ pH metry will be performed twice, at day 11 after the start of baclofen / placebo and with at least a 7 days wash out period between both study periods.

### Intervention

Twice a 24 hours ambulatory combined impedance measurement and pH metry (transnasally).

A dose of 3x20mg baclofen and a dose of 3xplacebo; the initial dose consisted of 3 x 5 mg baclofen. Every fourth day, the dose was increased by 5 mg three times daily until a dose of 20 mg three times daily was reached after 10 days.

## Contacts

### Public

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# Eligibility criteria

## Inclusion criteria

1. GERD patients (M/F) with typical heartburn symptoms at least 3 times weekly during the last 3months

2. Daily use of PPIs

3. 18-70 years

4. Hiatal hernia < 3 cm

5. Hiatus hernia > or = 3 cm

## Exclusion criteria

1. Thoracal or upper abdominal surgery

2. Use of drugs which influence gastrointestinal motility

3. Systemical illness which influence esophageal motility

4. Epilepsy

5. Renal function disorder

6. Pregnancy

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-03-2007 |
| Enrollment: | 30 |
| Type: | Actual |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 10-08-2008 |
| 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 | NL1340 |
| NTR-old | NTR1401 |
| Other | : MEC 06/183 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**
N/A