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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23260

Bron
Nationaal Trial Register

Verkorte titel
N/A

Aandoening

Gastroesophageal reflux disease (GERD), hiatal hernia

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Gastroenterology and Hepatology
Overige ondersteuning: AstraZeneca R&D, Mölndal, Sweden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2007
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	10-08-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1340
NTR-old	NTR1401
Ander register	: MEC 06/183
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A