De invloed van Gaviscon op de acid pocket en zure reflux.

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We hypothesize that after alginate intake a raft is formed in the proximal stomach proximal of the gastric acid pocket, and that this raft affects the gastric acid pocket regarding acidity, position and size leading to less acid reflux events.

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

Samenvatting

ID

NL-OMON25536

Bron
NTR

Aandoening

GERD
Gastro-esophageal reflux disease
GORZ
gastro-oesofageale reflux ziekte

Ondersteuning

Primaire sponsor: Prof. dr. G.E. Boeckxstaens
Academic Medical Center
Overige ondersteuning: Prof. dr. G.E. Boeckxstaens
Academic Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome is the number of acid reflux episodes detected on pH-impedance measurements.

Toelichting onderzoek

Achtergrond van het onderzoek

The gastric acid pocket is the most important source of refluxate. It is hypothesized that very commonly used alginate-antacid formulations form a floating raft on top of the acid pocket. This is however never visualized in vivo. To visualize the alginate raft formation and to assess the effect of this raft formation on reflux parameters, we aimed to perform a randomised controlled study in which we compared Gaviscon, a alginate-antacid formulation to Antagel, a commonly used antacid.
We will compare these two over the counter medications in one postprandial measurement using pH-impedance testing to detect reflux episodes.

Doel van het onderzoek

We hypothesize that after alginate intake a raft is formed in the proximal stomach proximal of the gastric acid pocket, and that this raft affects the gastric acid pocket regarding acidity, position and size leading to less acid reflux events.

Onderzoeksopzet

Patients undergo 1 postprandial measurement.

Onderzoeksproduct en/of interventie

1. The use of proton pump inhibitors has to be stopped 5-7 days prior to the study day;

2. On the study day, 350MBq Tc-pertechnetate is injected intravenously;

3. Randomized single oral administration of either 10 mL Gaviscon (Indium-labelled) or 10 mL Antagel;

4. Esophageal high-resolution manometry/pH-manometry to detect reflux eipsodes during 2 postprandial hours;

5. Scintigraphy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. GERD confirmed by pH-impedance (ph<4 in > 4,5 % of time or positive symptom association), or in patients with reflux esophagitis;

2. Written informed consent;

3. 18-75 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Surgery of the gastrointestinal tract other than appendectomy;

2. Inability to stop the use of proton pump inhibitors for one week;

3. Participation in another study with exposure to radiation;

4. Participation in another study within the last year;

5. Long segment of Barrett’s epithelium.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-06-2012
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-09-2012
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	NL3451
NTR-old	NTR3602
Ander register	MEC / CCMO : 11/279 / Nl37764.018.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Previous publications on this subject from our group:

Beaumont H, Bennink RJ, de Jong J et al. The position of the acid pocket as a major risk factor for acidic reflux in healthy subjects and patients with GORD. Gut 2010;59(4):441-51.

Rohof WO, Bennink RJ, Hirsch DP et al. Effect of azithromycin on acid reflux, hiatus hernia and proximal acid pocket in the postprandial period. Gut. 2012 Jan 20. [Epub ahead of print].