The effect of Iberogast on heartburn in patients with indigestion

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28589

Source
Nationaal Trial Register

Health condition

Functional dyspepsia, heartburn
Functionele dyspepsie, zuurbranden

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Amsterdam
Source(s) of monetary or material Support: Academisch Medisch Centrum Amsterdam
Bayer Vital GmbH

Intervention

Outcome measures

Primary outcome

- Gastro-oesophageal reflux disease symptom score improvement based on RDQ Questionnaire score

Secondary outcome

- Number of gastro-oesophageal reflux episodes during the 24-hr study (both mixed/liquid

reflux episodes and both acidic and non-acidic episodes)

- Proportion of acid and non-acid reflux episodes

- Total acid exposure time during 24-hour pH-impedance studies

- Quality of life (using the Quality of life in Reflux and Dyspepsia QoLRaD Questionnaire)

- Oesophageal sensitivity to acid perfusion

Time to symptoms during oesophageal acid exposure

Time to pain during oesophageal acid exposure (if present)

Symptom severity during oesophageal acid exposure (VAS)

Study description

Background summary

Rationale: Iberogast (STW5) is a multitarget herbal preparation which has been shown to effectively reduce symptoms in patients with functional dyspepsia. Many patients have, in addition to functional dyspepsia, heartburn complaints. Thus far, the mechanism of action of Iberogast in heartburn reduction is unknown. It has been demonstrated that the incidence of gastro-oesophageal reflux episodes is influenced by gastric motility and emptying. Since Iberogast affects proximal gastric motility, Iberogast could, in theory, result in a reduced incidence of reflux episodes in patients with dyspepsia. It is also possible that Iberogast could reduce the sensitivity of the oesophagus and stomach, and thus reduce perception of the refluxate. Given that the effect of proton pump inhibitors in dyspepsia with heartburn is small and the alternative treatment options are limited, a positive result could have a major effect on the treatment of heartburn in this patient population.

Objective: To assess the effect of Iberogast on heartburn, the incidence of reflux episodes and oesophageal sensitivity in patients with functional dyspepsia.

Study design: A prospective phase III study with a double blind placebo-controlled, randomized cross-over design.

Study population: Eighteen patients (> 18 years of age) with a history of dyspepsia and heartburn and a negative upper GI endoscopy will be invited to participate.

Intervention (if applicable): All patients will receive in one period either a placebo or Iberogast (20 drops three times daily) for at least 4 weeks, followed by a second period in which they will receive the other study medication (placebo if they received Iberogast during

the first period and Iberogast if they received placebo during the first period).

Main study parameters/endpoints: The main study parameter is the GORD symptom score improvement based on the RDQ Questionnaire score. Secondary endpoints are a decrease in reflux (measured with 24-hour oesophageal pH-impedance monitoring) and a decrease in oesophageal acid perception (acid perfusion test).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The subjects will have a total of 5 visits and will have to fill out 2 questionnaires on three separate occasions. There are no risks involved with oesophageal acid perfusion or with the 24-hour pH-impedance measurement. Both tests are only associated with discomfort in nose and throat upon placement of the catheter and with mild discomfort if the acid is perceived. Participants will be compensated financially for participation in the study and the findings could help treat future patients with similar complaints.

Study objective

We hypothesize that Iberogast reduces heartburn in patients with functional dyspepsia through an effect on both oesophageal hypersensitivity to acid and on the incidence of reflux episodes.

Study design

Day 1, 4 weeks, 4 week 1 day, 8 weeks, 8 week 1 day

Intervention

All patients will receive in one period either a placebo or Iberogast (STW5) (20 drops three times daily) for at least 4 weeks, followed by a second period in which they will receive the other study medication (placebo if they received Iberogast during the first period and Iberogast if they received placebo during the first period).

Contacts

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Eligibility criteria

Inclusion criteria

- Age above 18

- A history of dyspepsia (according to the Rome IV criteria) with heartburn

- Upper gastro-intestinal causes of the complaints excluded via gastroscopy with in addition an abdominal echography if found to be necessary by the physician

Exclusion criteria

- Surgery of the GI tract other than appendectomy or cholecystectomy

- Use of any medication with a potential effect on gastrointestinal motility, secretion or sensitivity that cannot be stopped for the duration of the study (e.g. proton pump inhibitors, H2-blockers, tricyclic antidepressants ...)

- Proton pump inhibitors cannot be stopped for 7 days before start of the study

- Known Barrett's oesophagus

- History of GI cancer

- Known allergy to one of the ingredients of Iberogast

- Known diabetes

- Severe and clinically unstable concomitant disease (e.g. liver, cardiovascular or lung disease, neurological or psychiatric disorders,
cancer or AIDS and other endocrine disorders)

- Pregnancy (women will be asked if they are pregnant)

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	10-04-2017
Enrollment:	18
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

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	NL6113
NTR-old	NTR6252
Other	2016-003739-40 : 59153

Study results

Summary results
N/A