

The effect of Iberogast on heartburn in patients with functional dyspepsia

Published: 01-03-2017

Last updated: 15-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON49070

Source

ToetsingOnline

Brief title

Iberogast and heartburn

Condition

- Gastrointestinal motility and defaecation conditions

Synonym

Heartburn, pyrosis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W, Bayer

Intervention

Keyword: heartburn, Iberogast, pyrosis, reflux

Outcome measures

Primary outcome

The main study parameter is the GORD symptom score improvement based on the 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 Short Form Nepean Dyspepsia Index (SF-NDI) 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)

Oesophageal motility

LOS-pressure

Oesophageal contractility

Study description

Background summary

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.

Study 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.

Intervention

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).

Study burden and risks

Discomfort associated with the oesophageal sensitivity test and side effects of Iberogast.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

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 deemed 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, antidepressants, prokinetics)
- * Proton pump inhibitors must be stopped at least 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 phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-06-2017
Enrollment:	18
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Iberogast
Generic name:	STW5
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO	
Date:	01-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	06-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2016-003739-40-NL
CCMO	NL59153.018.16