# The effect of Iberogast on heartburn in patients with functional dyspepsia

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

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|---|---|
| **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

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|---|---|
| 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

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

# Ethics review

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| 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 |