

Study of Gaviscon versus Omeprazole on pyrosis in patients with mODerate gastroesophageal reflux disease in which the current episode has not been treated (GOOD)

Submission date 28/10/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/11/2011	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/12/2020	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

In Western countries, 20% to 40% of adults suffer from episodes of heartburn due to gastroesophageal reflux disease (GERD), where acid leaks out of the stomach and up into the gullet, causing burning chest pain after eating. The aim of this study is to compare the short-term effectiveness and safety of two treatments for moderate GERD in a general practice setting: an alginate (Gaviscon®) and a proton pump inhibitor (omeprazole).

Who can participate?

Men and women aged between 18 and 60 who experience GERD/heartburn 2 to 6 days per week.

What does the study involve?

Participants are randomly allocated to be treated with either Gaviscon® or omeprazole.

What are the possible benefits and risks of participating?

Gaviscon may cause constipation, and omeprazole may cause diarrhea, constipation, stomach ache, nausea/vomiting, vertigo headaches, rash or itching.

Where is the study run from?

The study is a multicentre study carried out in France: 75 general physicians are involved as investigators.

When is the study starting and how long is it expected to run for?

August to December 2010.

Who is funding the study?

Reckitt Benckiser Healthcare France

Who is the main contact?

Dr Denis Pouchain

Contact information

Type(s)

Scientific

Contact name

Dr Denis Pouchain

Contact details

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94300

Additional identifiers

Clinical Trials Information System (CTIS)

2010-019563-11

Protocol serial number

RB10001

Study information

Scientific Title

Non-inferiority randomised, double-blind study comparing the efficacy of Gaviscon in oral suspension to 20mg omeprazole on pyrosis in patients with gastroesophageal reflux (GER) in which the current episode has not been treated with patient self-reporting questionnaires over a 14-day period.

Acronym

GOOD

Study objectives

The hypothesis is that the proton pump inhibitor (PPI) chosen within the context of the study will have a period of 2 days and a standard deviation of 1.0 days; the non-inferiority hypothesis will be achieved if Gaviscon does not differ by 0.5 of a day

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee to Protect People, Ile-de-France VIII [Comité de Protection des Personnes d'Ile-de-France VIII], 03/05/2010

Study design

Randomised double-blind controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Gastroesophageal reflux disease (GERD) with pyrosis

Interventions

Comparing Gaviscon oral solution to omeprazole 20 mg with daily measurements by the patient and two visits at Day 7 and Day 14 by the doctor.

Each patient agrees to be monitored by his/her investigator at 3 visits over 14 days: at the inclusion, at an interim visit on Day 7 and then at a final visit on Day 14. No laboratory or diagnostic examination will be requested throughout the duration of the study.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Gaviscon, omeprazole

Primary outcome(s)

Time period for obtaining 24 hour consecutive relief as evaluated on Day 7 using the patients' weekly diary - calculated through the daily recording of episodes of pyrosis by the patient in his /her self-questionnaire.

Key secondary outcome(s)

1. The number of patients without pyrosis pain at day 7
2. The number of patients presenting with greater comfort at day 7 and day 14 (on a 5 point Likert scale)

Completion date

13/12/2010

Eligibility**Key inclusion criteria**

1. Male or female patient
2. Aged 18 to 60 years
3. Patient with between 2 and 6 episodes of GER per week with pyrosis, with or without regurgitation
4. Patient not been treated for at least 2 months with an alginate/antacid combination or a

proton pump inhibitor (PPI)

5. Patient with signed informed consent form for participation in the study
6. Patient able to understand and fill out the study self-questionnaires
7. Patient affiliated with a national social security scheme
8. Women using a form of contraception

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

278

Key exclusion criteria

1. Patient with less than 2 episodes or over 6 episodes of GER with pyrosis per week
2. Patient being treated with an alginate/antacid combination and/or a PPI in the two months preceding the inclusion
3. Patient with mainly atypical, gastrointestinal or extra-intestinal symptoms, without symptoms of pyrosis
4. Patient treated with clopidogrel
5. Patient followed for a gastric or duodenal ulcer
6. Patient with surgery of the upper digestive tract
7. Patient with a neoplastic disorder of the upper digestive tract or ear, nose and throat
8. Patient with known hypersensitivity to one of the components of Gaviscon and/or omeprazole
9. Patient treated with atazanavir in combination with rotonavir
10. Patient treated with ketoconazole and/or itraconazole
11. Patient with known hypersensitivity to the benzimidazoles
12. Breastfeeding women or those with known pregnancy
13. Patient that refuses to participate in a clinical trial

Date of first enrolment

27/08/2010

Date of final enrolment

13/12/2010

Locations

Countries of recruitment

France

Study participating centre

1 Ter
Vincennes
France
94300

Sponsor information

Organisation

Reckitt Benckiser Healthcare (France)

Funder(s)

Funder type

Industry

Funder Name

Reckitt Benckiser Healthcare (France)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/02/2012	17/12/2020	Yes	No