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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

Registration date
09/11/2011

Last Edited
17/12/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
2010-019563-11

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 dÎle-de-France VIII], 03/05/2010

Study design
Randomised double-blind controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures

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)

Overall study start date
27/08/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

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)

Sponsor details
c/o Gaelle Rocheteau
15 rue Ampère
Massy Cedex
France
91748

Sponsor type
Industry

Website
http://www.rb.com/fr

Funder(s)

Funder type
Industry

Funder Name
Reckitt Benckiser Healthcare (France)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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