

Efficiency of Proton pump Inhibitors in Patients with gastro-oesophageal reflux symptoms

Submission date 24/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/04/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/09/2021	Condition category Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Efficiency of Proton pump Inhibitors in Patients with gastro-oesophageal reflux symptoms

Acronym

PIP study

Study objectives

1. To determine subgroups of patients with gastro-oesophageal reflux symptoms according to endoscopy and pH monitoring
2. To evaluate the differences in the subgroups of patients with Gastro-oesophageal Reflux Disease (GERD) symptoms in:
 - a. duration of Proton Pump Inhibitor (PPI) treatment (four versus eight weeks)
 - b. inflammatory reaction
 - c. prevalence of Helicobacter pylori
 - d. occurrence of symptoms
3. To evaluate treatment of GERD patients with PPIs for four or eight weeks in order to determine the effectiveness of the PPI treatment
4. To evaluate the effect of PPI treatment on:
 - a. symptom relief
 - b. inflammatory reaction in the oesophagus

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Medical Ethics Committee (Medisch Ethische Toetsings Commissie Erasmus MC) (ref: MEC-2005-141).

Study design

Randomised multicentre trial

Primary study design

Interventional

Secondary study design

Multi-centre

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Gastro-oesophageal reflux disease

Interventions

All patients will undergo a baseline endoscopy and follow up endoscopy with biopsies, then they all will undergo a wireless oesophageal 48 hour pH monitoring study, and finally these patients

will be randomised to either four weeks or eight weeks of 20 mg once daily rabeprazole treatment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rabeprazole

Primary outcome measure

Differences in the subgroups of patients with GERD symptoms in:

1. Duration of PPI treatment (four versus eight weeks)
2. Inflammatory reaction
3. Prevalence of H. pylori
4. Occurrence of symptoms

Secondary outcome measures

Effect of PPI treatment on:

1. Symptom relief
2. Inflammatory reaction in the oesophagus

Overall study start date

01/10/2005

Completion date

01/10/2008

Eligibility**Key inclusion criteria**

1. Aged 18 years or older
2. Symptoms of GERD as determined by the GERD-Health Related Quality of Life (HRQL) questionnaire (score more than or equal to 12)
3. Informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

415

Key exclusion criteria

1. Aged under 18 years
2. Unable to fill out questionnaire
3. Previous history of upper Gastro-Intestinal (GI) tract cancer
4. Previous history of achalasia
5. Previous surgery to the oesophagus or stomach
6. Endoscopically demonstrated and histologically proven complicated reflux disease (ulcer, stricture, Barretts esophagus)
7. Coagulation disorder if uncorrected at the time of endoscopy
8. Use of warfarin or other anti-coagulant medication if uncorrected at the time of endoscopy
9. Liver cirrhosis
10. Pregnancy and lactation
11. Contraindications to the study medication

Date of first enrolment

01/10/2005

Date of final enrolment

01/10/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

's-Gravendijkwal 230

Rotterdam

Netherlands

3015 CE

Sponsor information

Organisation

Erasmus Medical Center (The Netherlands)

Sponsor details

University Medical Center Rotterdam

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Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/content/englishindex.htm>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Industry

Funder Name

Janssen & Cilag B.V. (The Netherlands)

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