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

Submission date	Recruitment status	[ ] Prospectively registered
24/10/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/04/2007	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/09/2021	Digestive System	[ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s))
Effect of PPI treatment on:
1. Symptom relief
2. Inflammatory reaction in the oesophagus

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

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
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Sponsor information

Organisation
Erasmus Medical Center (The Netherlands)

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Industry

Funder Name
Janssen & Cilag B.V. (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration