Symptomatic response to proton pump inhibitor (PPI) in patients with non-ulcer dyspepsia

Submission date	Recruitment status	Prospectively registered
07/09/2010	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
08/09/2010	Completed	[X] Results
Last Edited	Condition category	Individual participant data
21/06/2011	Digestive System	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Efficacy of lansoprazole versus placebo in treatment of dyspepsia symptoms in endoscopy negative patients: a randomised controlled clinical trial

Study objectives

Proton pump inhibitor therapy is superior to placebo in treatment of symptoms of dyspeptic patients with normal endoscopy and negative for H. pylori.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Greater Glasgow Health Board - The West Ethical Committee on 17/061997 (ref: 97/106(2) (AHT /JR))

Study design

Interventional double-blind randomised placebo controlled single centre study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Dyspepsia, upper gastrointestinal tract disease

Interventions

Active: Lansoprazole 30 mg per day, once per day, per oral, for 14 days. Follow up for 14 days. Control: Placebo, once per day, per oral, for 14 days. Follow up for 14 days.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Lansoprazole

Primary outcome measure

Change in overall symptom score measured by modified Glasgow Dyspepsia Severity Score. All these measurements will be taken on baseline and at the end of 2 weeks.

Secondary outcome measures

Predictors of response to lansoprazole including symptom severity score, symptom characteristics, oesophageal 24h pH metry and oesophageal manometry profiles and body mass index (BMI). All these measurements will be taken on baseline.

Overall study start date

01/12/1997

Completion date

30/01/2000

Eligibility

Key inclusion criteria

- 1. Upper gastrointestinal (GI) symptoms of more than 3 months duration
- 2. No evidence of peptic ulcer disease, erosive oesophagitis or hiatus hernia in endoscopy
- 3. H. pylori negative on histology and urease test
- 4. Aged 24 72 years, either sex

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

105

Key exclusion criteria

- 1. Current use of non-steroidal anti-inflammatory drugs or other medication
- 2. Any recognised cause of upper GI symptoms

Date of first enrolment

01/12/1997

Date of final enrolment

30/01/2000

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
Institute of Cardiovascular and Medical Sciences
Glasgow
United Kingdom
G11 6NT

Sponsor information

Organisation

University of Glasgow (UK)

Sponsor details

University Avenue Glasgow Scotland United Kingdom G12 8QQ

Sponsor type

University/education

Website

http://www.gla.ac.uk/

ROR

https://ror.org/00vtgdb53

Funder(s)

Funder type

Industry

Funder Name

Wyeth Laboratories (UK) (ref: PV 214058)

Funder Name

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	01/04/2011		Yes	No