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

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

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
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

Scotland

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

Sponsor information

Organisation
University of Glasgow (UK)

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Industry

Funder Name
Wyeth Laboratories (UK) (ref: PV 214058)

Funder Name
Western Infirmary (UK) - Hospital Endowment Fund (ref: 1116/6)

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	01/04/2011		Yes	No