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The effect of pregabalin on human visceral pain hypersensitivity

Submission date 18/04/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/06/2008	**Overall study status** Completed	
Last Edited 23/11/2012	**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
Version 1 (03/04/07), MHRA 13904/0203/001-0001

Study information

Scientific Title

Effects of pregabalin on acid-induced oesophageal pain hypersensitivity in male and female healthy adult volunteers, as investigated in a single-centre, placebo-controlled, double-blind, randomised, two-period, cross-over study

Study objectives
Does pregabalin attenuate or prevent acid-induced oesophageal secondary hyperalgesia (pain)?

Please note that, as of 06/10/2008, the start and end dates of this trial have been updated from 01/05/2007 and 01/05/2008 to 01/04/2008 and 30/04/2009. The change is due to delays in preparation for the trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Research Ethics Committee. Date of approval: 04/07/2007 (ref: 07/MRE08/39). Amendment approved on 01/09/2007 (change of site from Manchester to London).

Primary study design
Interventional

Study design
Single-centre, placebo-controlled, double-blind, randomised, two-period, cross-over study.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acid reflux, epigastric pain.

Interventions
This is a cross-over study, and therefore the order of the treatment allocation is randomised. The wash-out period is 2 weeks.

Intervention: Five-day treatment with pregabalin
Days 1-3: 75 mg twice a day (bd)
Day 4: 150 mg bd
Day 5: 150 mg single dose in the morning

Placebo treatment: This will be administered as above.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pregabalin

Primary outcome(s)
Change in oesophageal pain threshold to electrical stimuli will be assessed by the Bernstein test. The participants will be asked to rate any discomfort or pain with a visual analogue scale before an acid infusion and 30 and 90 mins after the acid infusion. This test will be carried out at Visit 1, 2 and 3.

Timepoints:
Visit 1: Prior to randomisation
Visit 2: After the end of the first 5-day treatment (pregabalin or placebo)
Visit 3: At least 2 weeks after Visit 2 and at the end of the second 5-day treatment (pregabalin or placebo)

Key secondary outcome(s)
1. To assess whether psychological state or trait of the participants determine the magnitude of acid induced oesophageal hypersensitivity. The psychological state and trait of the participants will be assessed by questionnaires at Visit 1.
2. To assess whether an individual's autonomic profile (heart rate, blood pressure, etc) determines the magnitude of acid-induced oesophageal pain hypersensitivity and the effect of pregabalin. The autonomic measurements will be carried out at Visit 1, 2 and 3.

Timepoints:
Visit 1: Prior to randomisation
Visit 2: After the end of the first 5-day treatment (pregabalin or placebo)
Visit 3: At least 2 weeks after Visit 2 and at the end of the second 5-day treatment (pregabalin or placebo)

Completion date
30/04/2009

Eligibility

Key inclusion criteria
1. Age >18 and <60
2. Both males and females

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Currently on any medication
2. Known chronic medical illness
3. Previous or current psychiatric illness
4. Any upper gastrointestinal (GI) symptoms (heartburn, reflux-like, acid brash, epigastric pain, nausea and vomiting)
5. History of upper GI surgery
6. History of chest pain or discomfort
7. Anti-acid medication prescribed by doctor (proton pump inhibitors [PPI] or H2 antagonists)
8. Recent illnesses such as flu or cold in the preceding 2 weeks of the study
9. Pregnancy

Date of first enrolment
01/04/2008

Date of final enrolment
30/04/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Gastrointestinal physiology
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Barts and the London NHS Trust and Queen Mary, University of London (UK)

Funder(s)

Funder type
Industry

Funder Name

Pfizer UK Ltd (UK)

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	01/02/2012		Yes	No