

# The effect of pregabalin on human visceral pain hypersensitivity

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<b>Registration date</b> 16/06/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/11/2012	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**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**  
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).

## Study design

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

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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)

## **Secondary outcome measures**

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)

## **Overall study start date**

01/04/2008

## **Completion date**

30/04/2009

# **Eligibility**

## **Key inclusion criteria**

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

## **Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

16

**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**

England

United Kingdom

**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)

## Sponsor details

Joint Research and Development Office  
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## Sponsor type

Hospital/treatment centre

## Website

<http://www.bartsandthelondon.org.uk/research>

## Funder(s)

### Funder type

Industry

### Funder Name

Pfizer UK Ltd (UK)

## 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?
<a href="#">Results article</a>	results	01/02/2012		Yes	No

