# What constitutes a 'positive symptom index' for the diagnosis of gastro-oesophageal reflux-related pain?

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
30/09/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2004	Completed	[X] Results
<b>Last Edited</b> 30/04/2014	<b>Condition category</b> Digestive System	[] Individual participant data

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr J De Caestecker

#### Contact details

University Hospitals of Leicester c/o Research and Development Office Leicester General Hospital NHS Trust Leicester United Kingdom LE1 4PW +44 (0)116 258 4109 john.decaestecker@uhl-tr.nhs.uk

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# Study information

#### Scientific Title

#### **Study objectives**

To assess the best predictive value, using different methods of assessing symptom-reflux association, of a positive symptomatic response to acid suppression with standard doses of a proton pump inhibitor (PP).

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

#### 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

Gastro-oesophageal reflux disease

#### **Interventions**

Different methods of assessing symptom-reflux association.

#### Intervention Type

Other

#### Phase

**Not Specified** 

#### Primary outcome measure

Not provided at time of registration

#### Secondary outcome measures

Not provided at time of registration

## Overall study start date

01/08/2002

# Completion date

01/06/2006

# **Eligibility**

## Key inclusion criteria

Patient diagnosis of gastro oesophageal reflux related pain

## Participant type(s)

**Patient** 

#### Age group

**Not Specified** 

#### Sex

**Not Specified** 

## Target number of participants

Not provided at time of registration

#### Key exclusion criteria

Not provided at time of registration

#### Date of first enrolment

01/08/2002

#### Date of final enrolment

01/06/2006

# **Locations**

# Countries of recruitment

England

**United Kingdom** 

# Study participating centre University Hospitals of Leicester

Leicester United Kingdom LE1 4PW

# Sponsor information

## Organisation

Department of Health

### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

#### Sponsor type

Government

#### Website

http://www.dh.gov.uk/Home/fs/en

# Funder(s)

#### Funder type

Government

#### **Funder Name**

University Hospitals of Leicester NHS Trust (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?
Abstract results	abstract A-594	01/04/2007		No	No