

# HECTOR: Health Change and the Treatment of Reflux - does the prescription of proton pump inhibitor on demand for minor reflux disease affect motivation to correct cigarette smoking, obesity, alcohol abuse and inactivity?

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/10/2011	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Peter Isaacs

**Contact details**  
Gastroenterology Unit  
Blackpool, Fylde & Wyre Hospitals NHS Trust  
Whinney Heys Road  
Blackpool  
United Kingdom  
FY3 8NR  
+44 01253 303614  
[dr.isaacs@bfwhospitals.nhs.uk](mailto:dr.isaacs@bfwhospitals.nhs.uk)

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0301167004

## **Study information**

**Scientific Title**

**Study objectives**

What is the influence of on demand PPI prescribing on success in lifestyle change after brief interventions in patients with reflux disease who are obese, cigarette smokers or alcohol abusers?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised 2 arm trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Quality of life

**Participant information sheet**

**Health condition(s) or problem(s) studied**

Digestive System: Reflux

**Interventions**

Randomised 2 arm trial: either continued on demand PPI after one month or self medication with antacids after one month.

This trial was stopped as it failed to get primary care support.

**Intervention Type**

Drug

**Phase**

Not Specified

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

Proton pump inhibitors

**Primary outcome measure**

Success in weight reduction, reduction in cigarette consumption, maintenance of safe limits of alcohol consumption.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

22/06/2005

**Completion date**

22/07/2006

**Reason abandoned (if study stopped)**

Lack of facilities

**Eligibility****Key inclusion criteria**

1. >16 and <80 years
2. Obese with BMI >30 with heartburn

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

300 patients, 150 in each arm

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

22/06/2005

**Date of final enrolment**

22/07/2006

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

### Gastroenterology Unit

Blackpool

United Kingdom

FY3 8NR

# Sponsor information

## Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health (UK)

## Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

## Sponsor type

Government

## Website

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

# Funder(s)

## Funder type

Government

## Funder Name

Blackpool Fylde & Wyre Hospitals 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