

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?

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| Submission date 29/09/2006 | Recruitment status Stopped | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 29/09/2006 | Overall study status Stopped | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 11/10/2011 | Condition category 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

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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