

Helicobacter pylori eradication from general practice: clinical benefits and health economics

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/11/2011	Condition category 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
00001 RSU447971

Study information

Scientific Title

Study objectives

Helicobacter pylori is responsible for 95% of duodenal ulcers and most gastric ulcers. It may be responsible for some functional dyspepsia and may be a major factor in the aetiology of gastric cancer, the fourth commonest cause of death from malignancy in the UK. Approximately one person in forty of the UK population dies from a H. pylori associated disease. Successful eradication from the community should prevent duodenal ulcer, gastric ulcer and possibly gastric cancer. An average FHSA spends £4,000,000 per annum on acid reducing drugs. The Leeds FHSA expenditure is £5,000,000 per annum. The investigation of dyspepsia is also costly. The General Infirmary at Leeds serving a population of 400,000 spends £800,000 per annum on endoscopy and £90,000 per annum on barium meals. 10% of the population consult their general practitioner for dyspepsia every six months. Patients with dyspepsia have 2.6 times as many sick leave days as the background population matched for age, sex and occupational status. Primary prevention could lead to saving in drug expenditure, general practice consultations and hospital investigation. It should lead to reduction in the costs of sick pay, invalidity benefit and should reduce time lost from work.

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)

Other

Participant information sheet

Health condition(s) or problem(s) studied

Digestive system diseases: Peptic ulcer disease

Interventions

Treatment for H. pylori versus placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Absence of dyspepsia at two years
2. NHS dyspepsia costs for two years after the intervention

Secondary outcome measures

1. Dyspepsia subgroups
2. Quality of life
3. H. pylori eradication rates
4. Adverse events

Overall study start date

07/01/1994

Completion date

30/06/1998

Eligibility**Key inclusion criteria**

Patients aged 50-59 years from selected General Practice (GP) surgeries (including asymptomatic volunteers as well as patients with dyspepsia)

Participant type(s)

Patient

Age group

Adult

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

1. Severe mental illness
2. Severe medical illness that would make the subject unable to survive for two years
3. Allergy to proton inhibitors, clarythromycin or metronizadole
4. Unwillingness to abstain from alcohol whilst taking antibiotics
5. Pregnancy
6. Concomitant prescription of cisapride, warfarin, antihistamines or theophyllines

Date of first enrolment

07/01/1994

Date of final enrolment

30/06/1998

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Gastroenterology Unit

Birmingham

United Kingdom

B18 7QH

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

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dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (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?
Results article	results	13/05/2000		Yes	No
Results article	10 year follow-up results	01/12/2005		Yes	No