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

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2011	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Other

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Gastroenterology Unit
Birmingham
United Kingdom
B18 7QH

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

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