

A community study to assess the cost benefits of eradicating *Helicobacter pylori* in patients on long term H2 Receptor Antagonists (H2RA)

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/10/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

A community study to assess the cost benefits of eradicating *Helicobacter pylori* in patients on long term H2 Receptor Antagonists (H2RA)

Study objectives

Hospital based studies show that 'cure' of duodenal ulcer is possible if *H.pylori* is eradicated from the stomach. In Thornaby, there are two almost identical practices with large numbers of patients on H2RAs. The study aim is to recall all patients on long-term H2RAs, establish the diagnosis and treat *H. pylori* positive patients in one practice with Tripotassium dicitrato bismuthate, Metronidazole and Oxytetracycline. The incidence of *H.pylori* infection and success rate for eradicating the organism will be studied. One practice will act as a control. Patients will be interviewed by their own GP and treatment stopped. Investigation by gastroscopy, C13 urea breath test and serology will be at symptom relapse. An active 'placebo' regime will be given to patients from the control practice. All patients will be followed up for two years.

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)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Digestive system diseases: Peptic ulcer disease

Interventions

1. Treatment of *H. Pylori* positive patients with tripotassium dicitrato bismuthate, metronidazole and oxytetracycline.
2. Active 'placebo' regime

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Tripotassium dicitrato bismuthate, Metronidazole and oxytetracycline.

Primary outcome measure

Drug expenditure in the two practices will be compared and the number of patients restarting H2RA therapy.

Secondary outcome measures

Not provided at time of registration

Overall study start date

06/01/1993

Completion date

30/09/1997

Eligibility**Key inclusion criteria**

Patients on H2RAs

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

06/01/1993

Date of final enrolment

30/09/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Endoscopy Centre**

Middlesbrough

United Kingdom

TS4 3BW

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

+44 (0)20 7307 2622

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