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

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	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/10/2019	Nutritional, Metabolic, Endocrine	[ ] 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

93020032

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