ISRCTN54610315 https://doi.org/10.1186/ISRCTN54610315

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

Registration date
23/01/2004

Overall study status
Completed

Last Edited
24/10/2019

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)

Not provided at time of registration

Completion date
30/09/1997

Eligibility

Key inclusion criteria
Patients on H2RAs

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Endoscopy Centre
Middlesbrough
United Kingdom
TS4 3BW

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