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A population based randomised controlled trial of Helicobacter pylori eradication: impact on dyspepsia, quality of life and health

Submission date 03/08/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/08/2006	**Overall study status** Completed	
Last Edited 23/04/2008	**Condition category** Digestive System	

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
LIP/H2B/001

Study information

Scientific Title

Acronym
HEALTH

Study objectives
To determine the impact of a community-based Helicobacter pylori screening and eradication programme on the incidence of dyspepsia, resource use and Quality of Life (QoL), including a cost-consequences analysis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gained ethics approval from Frenchay Hospital LREC (reference number: 95/83 20/01/1996).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Dyspepsia

Interventions
Subjects were screened for H. pylori. Those who were positive were randomised between active eradication therapy or a placebo. Subjects were not randomised if they were found to be uninfected with H. pylori.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Helicobacter pylori

Primary outcome measure
Dyspepsia resolution at two years after randomisation.

Secondary outcome measures
1. Reduction in health service utilisation
2. Quality of life

Overall study start date
01/05/1996

Completion date
01/05/2006

Eligibility

Key inclusion criteria
1. Aged 20 to 59 years, male and female
2. Able to give written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1550

Key exclusion criteria
Any persons with the following conditions: pregnancy, breast feeding, severe renal impairment, adverse reaction to macrolide antibiotics, concurrent medication with wafarin, theophyllin, digoxin, terfendine, carbemazepine, ergot derivatives, bismuth compounds, acute porphyria.

Date of first enrolment
01/05/1996

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
Bristol
United Kingdom
BS8 2PR

Sponsor information

Organisation
NHS (South and West) (UK)

Sponsor details
Westward House
Lime Kiln Close
Stoke Gifford
Bristol
United Kingdom
BS12 6SR

Sponsor type
Government

Website
http://www.bristolswpct.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
NHS Executive (south and west)

Funder Name
Glaxo Wellcome 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:	12/06/2004		Yes	No
Results article	results:	28/01/2006		Yes	No
Results article	results:	15/04/2008		Yes	No