

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/08/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 23/04/2008	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Athene Lane

Contact details

University of Bristol
Canyge Hall
Whiteladies Road
Bristol
United Kingdom
BS8 2PR

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, terfenadine, carbamazepine, 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