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

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

# 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 Canynge Hall Whiteladies Road Bristol United Kingdom BS8 2PR

# Additional identifiers

Protocol serial number 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

#### Study type(s)

Treatment

#### 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(s)

Dyspepsia resolution at two years after randomisation.

#### Key secondary outcome(s))

- 1. Reduction in health service utilisation
- 2. Quality of life

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

**United Kingdom** 

England

# Study participating centre University of Bristol

Bristol United Kingdom BS8 2PR

# Sponsor information

#### Organisation

# Funder(s)

# Funder type

Government

#### Funder Name

NHS Executive (south and west)

#### Funder Name

Glaxo Wellcome UK

# **Results and Publications**

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