Helicobacter pylori Screening Study

Submission date	Recruitment status	Prospectively registered
09/03/2011	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
09/05/2011	Completed	Results
Last Edited	Condition category	Individual participant data
18/01/2024	Cancer	Record updated in last year

Plain English summary of protocol

Background and study aims

Helicobacter pylori is a bacterial infection that increases the risk of stomach cancer. The aim of this study is to find out whether screening for and eradicating H. pylori infection in healthy middle aged people can reduce the subsequent incidence of stomach cancer.

Who can participate?

Men aged 35-69 and women aged 45-69 attending a Bupa Wellness Centre for a health screen.

What does the study involve?

Participants are randomly allocated to one of two groups. Participants in one group are tested for H. pylori and, if found to be infected, are offered a one-week course of drug treatment to eradicate the infection (oral metronidazole, clarithromycin and lansoprazole). Participants in the other group do not receive any screening or treatment. All participants are followed up for 15 years or more to assess the incidence of deaths from stomach cancer.

What are the possible benefits and risks of participating? Not provided at time of registration

Where is the study run from? Queen Mary, University of London (UK)

When is the study starting and how long is it expected to run for? April 1997 to January 2025

Who is funding the study?

- 1. Cancer Research UK (CRUK) (UK)
- 2. Bupa Foundation (UK)

Who is the main contact?

- 1. Prof. Nicholas Wald
- 2. Prof. Joan Morris jmorris@sgul.ac.uk

Contact information

Type(s)

Scientific

Contact name

Prof Nicholas Wald

Contact details

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Type(s)

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Prof Joan Morris

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Additional identifiers

Protocol serial number

SP/1793/0501 from 1/7/97, SP/1793/0502 from 1/7/99, SP/1793/0503 from 1/7/00, SP/1793 /0504 from 1/3/01, SP/1793/0505 from 1/7/01, C5070/A3021 from 1/7/02, C5070/A5429 from 1 /7/04, C5070/A11090 1/1/09

Study information

Scientific Title

A randomised trial of the effects of screening for and treating Helicobacter pylori

Acronym

HPSS

Study objectives

HPSS was designed to assess whether screening for and eradicating H. pylori infection in healthy middle aged people can reduce the subsequent incidence of stomach cancer

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Clinical Research Ethics Committee of the Royal College of General Practitioners, 28/11/1995, ref: CREC/1995/33(28)

Study design

Cluster randomized open controlled multi-centre trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of stomach cancer

Interventions

Participants seen in treatment weeks, if H. pylori positive, were offered a one week course of eradication therapy comprising twice-daily oral metronidazole 400 mg, clarithromycin 250 mg and lansoprazole 30 mg.

No screening or treatment was offered to control participants.

Follow-up is for all participants, for 15 years or more after recruitment, with notifications of all cancers and of deaths by cause from the Information Centre for Health and Social Care and the General Register Office for Scotland.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Incidence of and death from stomach cancer

Key secondary outcome(s))

- 1. Incidence of and death from oesophageal cancer
- 2. Death from ischaemic heart disease
- 3. Death from gastric bleed or peptic ulcer

Completion date

01/01/2025

Eligibility

Key inclusion criteria

- 1. Healthy NHS-registered UK residents
- 2. Male participants aged 35-69
- 3. Female participants aged 45-69
- 4. Patients attending a Bupa Wellness Centre for a health screen

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

35 years

Upper age limit

69 years

Sex

All

Total final enrolment

62454

Key exclusion criteria

- 1. On medication which may interact dangerously with metronidazole, clarithromycin or lansoprazole (according to Appendix 1 of the British National Formulary)
- 2. A history of intolerance or allergy to metronidazole, clarithromycin or lansoprazole or other drugs of the same class as any of these three drugs
- 3. Currently being treated for an ulcer
- 4. On a proton-pump inhibitor or H2 antagonist
- 5. Having been tested or treated for H. pylori infection in the previous three years
- 6. Pregnancy or breastfeeding
- 7. Past history of or current gastric cancer
- 8. Life-threatening illness
- 9. Porphyria
- 10. Prolongation of QT interval
- 11. Current clinical liver disease or a history of severe liver disease

Date of first enrolment

07/04/1997

Date of final enrolment

31/01/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Centre for Environmental and Preventive Medicine
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation

Queen Mary University of London (UK)

ROR

https://ror.org/026zzn846

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK) (ref no C5070/A5429)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

Bupa Foundation (UK) (Award letter 08/12/1997)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Participant information sheetParticipant information sheet11/11/202511/11/2025NoYes