

Helicobacter pylori Screening Study

Submission date 09/03/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/01/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

Incidence of and death from stomach cancer

Secondary outcome measures

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

Overall study start date

07/04/1997

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

Age group

Adult

Lower age limit

35 Years

Upper age limit

69 Years

Sex

Both

Target number of participants

56,000

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

England

United Kingdom

Study participating centre

Centre for Environmental and Preventive Medicine

London

United Kingdom

EC1M 6BQ

Sponsor information

Organisation

Queen Mary University of London (UK)

Sponsor details

Research and Development

Joint Research Office

24-26 Walden Street

Whitechapel

London

England

United Kingdom

E1 2AN

Sponsor type

University/education

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, 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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

01/04/2026

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