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Helicobacter pylori Screening Study

Submission date 09/03/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/05/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 18/01/2024	**Condition category** Cancer	[_] Individual participant data [_] 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

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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