

A prospective randomised controlled trial of open access endoscopy and near patient testing for *Helicobacter pylori* antibodies in primary care

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/04/2009	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PSI03-07

Study information

Scientific Title

Study objectives

Dyspepsia is common, with an incidence of 2 'new episodes' per 1000 population per year. However, dyspepsia is also a lifelong intermittent and relapsing disorder, with as many as a third of the adult population suffering dyspeptic symptoms in a year. General practitioners have been encouraged to endoscope patients over the age of 50 years, particularly those with recent onset or continuous symptoms, on account of the potential to detect early gastric cancer. However, early gastric cancer is rare and a large number of patients would need to be investigated to detect one case. Malignancy is extremely rare under the age of 50 and current guidelines have concentrated on reducing endoscopy workload by filtering out patients testing negative for *Helicobacter pylori*, on the basis that they are unlikely to have peptic ulceration, and could be treated with empirical acid suppression, rather than *H. pylori* eradication therapy.

This study was conducted as two identical randomised controlled trials (RCTs), the intervention differing by the age of the patient:

1. For patients of 50 years and over we aimed to determine the cost-effectiveness of initial endoscopy compared to usual management
2. For patients under the age of 50 years we aimed to determine the cost-effectiveness of the *H. pylori* 'test and endoscope' strategy for managing dyspepsia

Ethics approval required

Old ethics approval format

Ethics approval(s)

Obtained from all local research ethics committees

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Peptic ulcer disease

Interventions

Under 50 years: Near patient testing for H. pylori (Helisal rapid blood, Cortecs diagnostics, UK) and open-access endoscopy if positive

Over 50 years: initial open access endoscopy

Controls: prescribing or specialist referral at GP's discretion

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Cost-effectiveness based on symptomatic improvement and health resource utilisation for dyspepsia at 12 months.

Secondary outcome measures

1. Quality of life (QoL)
2. Patient satisfaction

Overall study start date

01/03/1995

Completion date

01/10/1999

Eligibility

Key inclusion criteria

1. Dyspeptic patients
2. Aged 18 years and over (either sex)
3. Helicobacter pylori positive

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

430

Key exclusion criteria

1. Previous endoscopy
2. Positive barium meal examination in the past three years
3. Unable to give informed consent
4. Unfit for endoscopy

Date of first enrolment

01/03/1995

Date of final enrolment

01/10/1999

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

The Department of Primary Care and General Practice

Birmingham

United Kingdom

B15 2TT

Sponsor information**Organisation**

Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

NHS Primary and Secondary Care Interface National Research and Development Programme (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	14/04/2001		Yes	No