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# 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

**Registration date**
23/01/2004

**Overall study status**
Completed

**Last Edited**
01/04/2009

**Condition category**
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

**Protocol serial number**
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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

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

### Key secondary outcome(s)
1. Quality of life (QoL)
2. Patient satisfaction

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Sex
All

### 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
United Kingdom

England

### Study participating centre
**The Department of Primary Care and General Practice**
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## Sponsor information

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

## Funder(s)

### Funder type
Government

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