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# Randomised trial comparing the efficacy and costs of endoscopy with Helicobacter pylori testing versus non-invasive Helicobacter pylori testing alone in the management of dyspepsia

**Submission date**
25/04/2003

**Recruitment status**
No longer recruiting

**Registration date**
25/04/2003

**Overall study status**
Completed

**Last Edited**
27/08/2009

**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

**Contact name**
Prof Kenneth McColl

**Contact details**
University Dept of Medicine and Therapeutics
University of Glasgow
44 Church Street
Glasgow
United Kingdom
G11 6NT
+44 (0)141 211 2513
K.E.L.McColl@clinmed.gla.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
HTA 94/41/17

# Study information

### Scientific Title

### Study objectives
Dyspepsia is a common problem in the U.K. and accounts for 10% of GP attendance and 30% of hospital GI clinic referrals. Patients with persisting dyspepsia are investigated by upper GI endoscopy in order to diagnose the underlying cause and determine the most appropriate management. The demand for diagnostic endoscopy continues to increase and currently costs the NHS more than 100 million per year. The procedure also causes the patient significant discomfort and inconvenience.

Studies in our own unit and other centres suggests that non-invasive Helicobacter pylori testing might replace endoscopy in determining the management of a substantial proportion of patients with simple dyspepsia. In order to asses this we propose a randomised controlled trial comparing endoscopy versus non-invasive H.pylori testing in patients with dyspepsia who are less than 55 years and have no sinister symptoms. The study will also allow identification of the patients who will benefit most from the non-endoscopic management. The ability to replace endoscopy by non-invasive test should result in major savings to the health budget and save the patient the discomfort of invasive procedure. It will also allow most dyspeptic patients to be managed definitively in primary care and without the need to attend hospital clinics or endoscopy units.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration.

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Diagnostic

### Participant information sheet

### Health condition(s) or problem(s) studied
Digestive system diseases: Peptic ulcer disease

### Interventions
1. Endoscopy
2. Non-invasive H. pylori testing

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Glasgow dyspepsia severity score at one year.

### Secondary outcome measures
Use of medical resources, patient oriented outcomes, and safety were also assessed.

### Overall study start date
01/08/1997

### Completion date
31/08/2001

## Eligibility

### Key inclusion criteria
Patients with dyspepsia who are less than 55 years old with no sinister symptoms

### Participant type(s)
Patient

### Age group
Adult

### Sex
Not Specified

### Target number of participants
708

### Key exclusion criteria
Not provided at time of registration.

### Date of first enrolment
01/08/1997

### Date of final enrolment
31/08/2001

# Locations

**Countries of recruitment**
Scotland

United Kingdom

**Study participating centre**
**University Dept of Medicine and Therapeutics**
Glasgow
United Kingdom
G11 6NT

# Sponsor information

**Organisation**
Department of Health (UK)

**Sponsor details**
Quarry House
Quarry Hill
Leeds
United Kingdom
LS2 7UE
+44 (0)1132 545 843
Sheila.Greener@doh.gsi.gov.uk

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/en/index.htm

**ROR**
https://ror.org/03sbpja79

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Health Technology Assessment Programme - HTA (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 | 27/04/2002 | | Yes | No |