

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	☐ Prospectively registered ☐ Protocol
Registration date 25/04/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/08/2009	Condition category Digestive System	☐ 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
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 assess 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

Study type(s)

Diagnostic

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(s)

Glasgow dyspepsia severity score at one year.

Key secondary outcome(s)

Use of medical resources, patient oriented outcomes, and safety were also assessed.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

Scotland

Study participating centre

University Dept of Medicine and Therapeutics

Glasgow

United Kingdom

G11 6NT

Sponsor information

Organisation

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (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	27/04/2002		Yes	No