

A randomised trial of early endoscopy, *Helicobacter pylori* (Hp) testing or empiric treatment for dyspepsia

Submission date 23/01/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 01/04/2009	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

PSI03-01

Study information

Scientific Title

Study objectives

A randomised trial of early endoscopy or testing for helicobacter pylori in patients newly consulting for dyspepsia. The trial will establish the benefits of early endoscopy versus two management strategies based on testing for helicobacter pylori in primary care compared to conventional empiric treatment with gastric acid reducing drugs. Benefits will be assessed in terms of symptom relief, patient satisfaction and disability, reconsultation rates, drug prescribing and diagnostic yield.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Peptic ulcer disease

Interventions

1. Early endoscopy
2. Management strategies based on testing for Helicobacter pylori in primary care
3. Conventional empiric treatment with gastric acid reducing drugs (control)

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Diagnosis
2. Drugs prescribed
3. Repeat consultations
4. Need for further investigation/referral
5. Symptom response
6. Self-medication
7. Time off work
8. Patient satisfaction and quality of life (36-item Short Form Health Survey [SF-36])

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/11/1998

Eligibility

Key inclusion criteria

Patients newly presenting with dyspeptic symptoms

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/05/1995

Date of final enrolment

01/11/1998

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Faculty of Medicine

Nottingham

United Kingdom

NG7 2UH

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	01/01/2009		Yes	No