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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 01/04/2009	**Condition category** Digestive System	

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

Study design
Randomised controlled trial

Primary study design
Interventional

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 dyspectic 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