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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

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 measure
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])

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/1995

Completion date
01/11/1998

Eligibility

Key inclusion criteria
Patients newly presenting with dyspectic symptoms

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Primary and Secondary Care Interface National Research and Development Programme (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	01/01/2009		Yes	No