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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/01/2004		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
23/01/2004	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
01/04/2009	Digestive System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Kev 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

NG7 2UH

United Kingdom

Study participating centre Faculty of Medicine Nottingham United Kingdom

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