ISRCTN91662361 https://doi.org/10.1186/ISRCTN91662361

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

Registration date
25/04/2003

Overall study status
Completed

Last Edited
27/08/2009

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 asses 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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 measure
Glasgow dyspepsia severity score at one year.

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

Overall study start date
01/08/1997

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

Age group
Adult

Sex
Not Specified

Target number of participants
708

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
Scotland

United Kingdom

Study participating centre
University Dept of Medicine and Therapeutics
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Sponsor information

Organisation
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

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