Consultants and Physiology technicians: A comparative analysis of treatment pathways for patients with gastro oesophageal reflux disease and dysphagia.

Submission date	Recruitment status	Prospectively registered
30/09/2005	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
30/09/2005	Stopped	Results
Last Edited	Condition category	Individual participant data
21/04/2011	Digestive System	Record updated in last year

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 N0084144516

Study information

Scientific Title

Study objectives

Proposing an alternative fast track route of treatment. Patients suspected of having an oesophageal disorder and/or GORD would be referred via the consultant surgeon/physician /upper GI nurse practitioner or GP.

Patients would initially undergo an endoscopy. After an endoscopy has excluded any serious and significant pathology, the technician would carry out oesophageal manometry and 24 hour pH studies. After performing the studies the technician will then make a diagnosis, based upon the results. Upon an abnormal diagnosis, of oesophagical function or GORD made, patients will then be asked to take part in the proposed study and will be randomised to either consultant or technician mediated treatment.

Resources: investigator's time. Per patient: one hour of investigator's time. Pharmacy department will issue medication.

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)

Not Specified

Health condition(s) or problem(s) studied

Digestive System: Gastro-oesophageal reflux disease (GORD)

Interventions

Randomisation to either consultant or technician mediated treatment.

Added July 2008: the trial was stopped due to lack of funding.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/10/2004

Reason abandoned (if study stopped)

Lack of funding

Eligibility

Key inclusion criteria

Not provided at time of registration

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

01/06/2002

Date of final enrolment

01/10/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre GI Physiology Department

Hull United Kingdom HU16 5JQ

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

The North and South Bank Research and Development Consortium (UK)

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration