ISRCTN85216012 https://doi.org/10.1186/ISRCTN85216012

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

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 21/04/2011	**Condition category** Digestive System	[ ] Individual participant data [ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Approximately 200 patients

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
England

United Kingdom

Study participating centre
GI Physiology Department
Hull
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Sponsor information

Organisation
Department of Health

Sponsor details
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

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