

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Warren Jackson

### Contact details

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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

United Kingdom

HU16 5JQ

# Sponsor information

## Organisation

Department of Health

## Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

## 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