Valved oesophageal stents in patients with oesophageal carcinoma.

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/09/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
17/05/2012	Cancer			

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

N0013160111

Study information

Scientific Title

Study objectives

Whether a valve in oesophageal stent design is beneficial?

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

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Oesophageal cancer

Interventions

Following stent insertion, symptomatic reflux may occur, to evaluate whether a valve may prevent this we are conducting this randomised controlled trial comparing valveless stents versus a stent with a valve. All patients entered into this study will have cancer obstructing the lower oesophagus and will be treated with metallic stents projecting into the stomach. There are two groups: One group will receive stents that have a valve that is designed to prevent stomach contents reaching the oesophagus. The other will have stents without a valve. We will look at how well the stents work at stopping reflux, how well they receive dysphagia (difficulty in swallowing) and what the complications are in each group. Subjects will be randomised using a book of random numbers.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Dysphagia scores, barium reflux.

Secondary outcome measures

Not provided at time of registration

Overall study start date

27/01/2005

Completion date

27/01/2006

Eligibility

Key inclusion criteria

Randomised between stents with no valve but prescribed Omeprazole and stent with valve. Approx. 50 patients.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

50

Key exclusion criteria

- 1. Pregnant women
- 2. Patients under 18 years of age
- 3. Patients unfit for stent insertion

Date of first enrolment

27/01/2005

Date of final enrolment

27/01/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Department of Radiology London United Kingdom SE1 7EH

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

Guy's and St. Thomas' NHS Foundation Trust (UK)

Funder Name

Own account

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2008		Yes	No