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Valved oesophageal stents in patients with oesophageal carcinoma.

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] 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

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Dysphagia scores, barium reflux.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

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

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