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Oesophageal stents with anti-reflux valve for treatment of tumour of the oesophageal junction

Submission date 30/09/2004	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Stopped	
Last Edited 19/10/2012	**Condition category** 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
N0226127789

Study information

Scientific Title

Study objectives
To establish whether there is any difference in the performance of two CE-marked, commercially available self expanding oesophageal stents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Cancer: Oesophageal

Interventions
Please note that this trial was stopped as the devices to be used were no longer available.

All patients will have stents inserted according to integrated care pathway, the only difference from standard procedure will be formal randomisation from a schedule provided by medical statistics rather than random stent allocation.
CE-marked, commercially available self expanding oesophageal stent 1 vs CE-marked, commercially available self expanding oesophageal stent 2.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Development of gastro-oesophageal reflux symptoms requiring treatment

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

Completion date
01/09/2004

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
25 patients in each arm. 50 consecutive patients to be recruited after a positive decision for stent insertion has been made - all patients with a tumour site at or extending to the gastro-oesophageal (GO)-junction

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
01/09/2003

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South Manchester University Hospitals NHS Trust
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
South Manchester University Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration