ISRCTN83742179 https://doi.org/10.1186/ISRCTN83742179

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

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

**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**

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

### 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
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 measure
Development of gastro-oesophageal reflux symptoms requiring treatment

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/09/2003

### 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

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
50

### 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
England

United Kingdom

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

# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

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

# Funder(s)

**Funder type**
Government

**Funder Name**
South Manchester University Hospitals NHS Trust (UK)

# 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