

# Valved oesophageal stents in patients with oesophageal carcinoma.

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/05/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**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?
<a href="#">Results article</a>	results	01/05/2008		Yes	No