# Valved oesophageal stents in patients with oesophageal carcinoma.

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
30/09/2005		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
30/09/2005		[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

Prof Andreas Adam

#### Contact details

Department of Radiology F01 Lambeth Wing St Thomas's Hospital Lambeth Palace Road London United Kingdom SE1 7EH +44 (0)20 7188 5550 andy.adam@kcl.ac.uk

# 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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes