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

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Hans Ulrich Laasch

#### Contact details

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# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

# 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