ISRCTN78960892 https://doi.org/10.1186/ISRCTN78960892

Valved oesophageal stents in patients with oesophageal carcinoma.

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Dysphagia scores, barium reflux.

Secondary outcome measures
Not provided at time of registration

Overall study start date
27/01/2005

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

Age group
Adult

Sex
Both

Target number of participants
50

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
England

United Kingdom

Study participating centre
Department of Radiology
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2008		Yes	No