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A randomised trial comparing argon plasma coagulation (APC) and self-expanding metal stents (SEMS) in oesophageal cancer

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 22/09/2014	**Condition category** 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

N0077122803

Study information

Scientific Title

Study objectives
To test the hypothesis that early stent insertion is superior to argon plasma coagulation of oesophageal cancer in the palliative treatment of malignant dysphagia.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer: oesophageal

Interventions
Patients not eligible for surgery, presenting with dysphagia (score of >2) will be randomised to primary treatment with either APC or SEMS. Dysphagia management will be as per randomised arm until clinical indication to crossover. Where the stricture prevents passage of the scope into the stomach, through-the-scope balloon will be performed. Either APC or stenting will be used to overcome tumour obstruction of the oesophagus. Providing the patient is able to swallow liquids after the procedure, they will be discharged for reassessment at 1 week, at which stage a second treatment can be considered to achieve a dysphagia score of 2. If this is not achieved with two treatments, crossover to stenting should be considered. Those patients who have had successful APC will attend the endoscopy unit for repeat treatments at 4 weekly intervals unless dysphagia deems earlier intervention appropriate. Stent patients will be assessed at 1 week, then monthly with quality of life questionnaires in the clinic. Patients requiring further intervention after SEMS insertion due to overgrowth would be considered for re-stenting; those

with tumour ingrowth would crossover to APC. Quality of life will be quantified using EORTC QLQ-C30 and QLQ-OES, prior to intervention and at 4 weekly intervals. Dysphagia scores will be recorded prior to primary intervention, at 1 week after intervention and at 4 weekly intervals. At randomisation, length and position to tumour, histology, disease staging, body mass index and Karnofsky performance score will be recorded.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Comparison of reductions in dysphagia scores between the two groups
2. Comparison of quality of life scores between the two groups
3. Number of interventions per arm and consequent cost analysis

Secondary outcome measures
Not provided at time of registration

Overall study start date
04/12/2002

Completion date
04/12/2005

Eligibility

Key inclusion criteria
Patients with oesophageal cancer who are not eligible for surgery following multi-disciplinary team discussion who are unable to swallow semi-solid food

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
04/12/2002

Date of final enrolment
04/12/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southern Derbyshire Acute Hospitals NHS Trust
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Department of Health (UK)

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

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Southern Derbyshire Acute 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