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

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

**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**
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

## Primary study design
Interventional

## Study design
Randomised controlled trial

## Study type(s)
Treatment

## 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(s)

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

### Key secondary outcome(s)
Not provided at time of registration

### 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

### Healthy volunteers allowed
No

### Age group
Not Specified

### Sex
Not Specified

### 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
United Kingdom

England

### Study participating centre
**Southern Derbyshire Acute Hospitals NHS Trust**
Derby

United Kingdom
DE22 3NE

# Sponsor information

**Organisation**
Department of Health (UK)

# Funder(s)

**Funder type**
Government

**Funder Name**
Southern Derbyshire Acute Hospitals NHS Trust (UK)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration