

# A pragmatic randomised controlled trial of the cost-effectiveness of palliative therapies for patients with oesophageal cancer

|  |   |   |
|--|---|---|
| <b>Submission date</b><br>25/04/2003   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>25/04/2003 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>08/11/2022       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Mr Michael Griffin

### Contact details

Surgical Gastroenterology Department  
Newcastle University and The Royal Victoria Infirmary  
Westgate Road  
Newcastle upon Tyne  
United Kingdom  
NE4 6BE  
+44 (0)191 282 0234  
none@example.com

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

A pragmatic randomised controlled trial of the cost-effectiveness of palliative therapies for patients with oesophageal cancer

### Study objectives

The aim of the study is to assist health purchasers in deciding between different palliative therapies for patients with oesophageal cancer. Two new types of oesophageal stent will be compared to other widely used methods of palliation: Insertion of rigid oesophageal endoprotheses and non-stenting endoscopic treatments. A multi-centred pragmatic prospective trial involving six centres and 240 patients is proposed to compare costs and benefits to patients of these therapies in terms of relief of symptoms, incidence of early and late complications and improvement in swallowing ability and quality of life. The study will estimate the total treatment costs to the NHS and demonstrate any differences in clinical effectiveness as well as the most cost-effective palliative therapy for malignant dysphagia when all complications and cost of subsequent additional treatments are taken into account.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The study was approved by the Multicentre Research and Ethics Committee (MREC) on 8 October 1998 (ref: MREC/98/3/51)

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Quality of life

### Participant information sheet

### Health condition(s) or problem(s) studied

Cancer (neoplasms): Oesophagus

### Interventions

Oesophageal cancer. Two new types of oesophageal stent will be compared to other widely used methods of palliation: Insertion of rigid oesophageal endoprotheses and non-stenting endoscopic treatments.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Relief of symptoms, incidence of early and late complications and improvement in swallowing ability and quality of life. The study will also estimate the total treatment costs to the NHS and demonstrate any differences in clinical effectiveness as well as the most cost-effective palliative therapy for malignant dysphagia when all complications and cost of subsequent additional treatments are taken into account.

**Secondary outcome measures**

Not provided at time of registration.

**Overall study start date**

01/10/1998

**Completion date**

30/09/2001

**Eligibility****Key inclusion criteria**

Patients with oesophageal cancer

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Both

**Target number of participants**

217

**Key exclusion criteria**

Not provided at time of registration.

**Date of first enrolment**

01/10/1998

**Date of final enrolment**

30/09/2001

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Surgical Gastroenterology Department**

Newcastle upon Tyne

United Kingdom

NE4 6BE

## **Sponsor information**

**Organisation**

Department of Health (UK)

**Sponsor details**

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

+44 (0)1132 545 843

Sheila.Greener@doh.gsi.gov.uk

**Sponsor type**

Government

**Website**

<http://www.dh.gov.uk/en/index.htm>

**ROR**

<https://ror.org/03sbpja79>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

| Output type                     | Details       | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | HTA monograph | 01/02/2005   |            | Yes            | No              |