

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

Submission date 25/04/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/04/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/11/2022	Condition category Cancer	☐ Individual participant data

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
HTA 96/06/07

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)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

30/09/2001

Eligibility

Key inclusion criteria

Patients with oesophageal cancer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

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

United Kingdom

England

Study participating centre

Surgical Gastroenterology Department

Newcastle upon Tyne

United Kingdom

NE4 6BE

Sponsor information

Organisation

Department of Health (UK)

ROR

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

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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?
Results article	HTA monograph	01/02/2005		Yes	No