

Cancer of the oesophagus or gastricus: new assessment of the technology of endosonography

Submission date 19/02/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/02/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/01/2022	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-an-ultrasound-during-endoscopy-to-assess-cancer-of-the-oesophagus>

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00629863

Protocol serial number

HTA 01/01/03

Study information

Scientific Title

Cancer of the oesophagus or gastricus: new assessment of the technology of endosonography

Acronym

COGNATE

Study objectives

What is the role of Endoscopic UltraSound (EUS) in the staging and subsequent management of patients with gastric and oesophageal cancer?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Multicentre Research Ethics Committee (MREC), 14/06/2004, ref: 04/MRE10/10

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer of the oesophagus or gastricus

Interventions

Patients will be randomised to receive EUS or not after standard staging investigations. The standard staging algorithm has been selected on the basis of most common current practice identified by the Scottish Audit of Gastro-Oesophageal Cancer (SAGOC). In the EUS group a decision will be made after the EUS investigation to allocate the patients to one of the three treatment groups. Allocation will be based on the results of standard investigations in the control group.

The three treatment groups are:

1. Patients thought to have mucosal tumours - these will be treated with Endoscopic Mucosal Resection (EMR) and the surrounding mucosa ablated
2. Patients with tumours which are thought to be resectable - these will be treated with surgery and neo-adjuvant chemotherapy
3. Patients with advanced localised disease in whom it is not thought that a complete resection is possible - such patients will be treated using a multi-modality approach. In patients with gastric cancers this may involve palliative surgery

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Primary outcome measure as of 16/09/2008:
Survival, recorded until the end of trial

Previous primary outcome measure:
Survival

Key secondary outcome(s)

Secondary outcome measures as of 16/09/2008:

1. Treatment selection
2. Complete resection rate
3. Quality of life, assessed using the Euroqol EQ-5D and Functional Assessment of Cancer Therapy (FACT1 and FACT2) after 1, 3, 6, 12, 18, 24 and 36 months after randomisation
4. Health resource utilisation. Collection of clinical data on treatment, primary and secondary care use, drug use, etc will be carried out until the end of trial.

Previous secondary outcome measures:

1. Treatment selection
2. Complete resection rate
3. Quality of life
4. Health resource utilisation

Completion date

31/01/2010

Eligibility**Key inclusion criteria**

1. Patients with T1 tumors localised to the gastric or oesophageal mucosa who may benefit from endoscopic treatment
2. Patients with a range of tumours whom Endoscopic UltraSounds (EUS) may identify either as likely to benefit from 'curative' surgery or likely to have residual disease after major surgery with its attendant risks
3. Patients with T3 or T4 tumours whom EUS may identify as likely to benefit from multi-modal treatment or not

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. World Health Organisation (WHO) status three or above
2. Patients with metastatic disease
3. Unfit for surgery

Date of first enrolment

01/02/2004

Date of final enrolment

31/01/2010

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre

Bangor University

Gwynedd

United Kingdom

LL57 2PZ

Sponsor information**Organisation**

Bangor University (UK)

ROR

<https://ror.org/006jb1a24>

Funder(s)**Funder type**

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2013		Yes	No
Plain English results			20/01/2022	No	Yes