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

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

# 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

#### Contact name

Dr Angela Gliddon

#### Contact details

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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

# Study design

Randomised controlled trial

# Primary study design

Interventional

# 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results			20/01/2022	No	Yes