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

Submission date	Recruitment status	[_] Prospectively registered
19/02/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/02/2004	Completed	[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
Bangor University
Normal Site
Bangor
Gwynedd
United Kingdom
LL57 2PZ
+44 (0)1248 382224
a.e.gliddon@bangor.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00629863

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Previous primary outcome measure:
Survival

Secondary outcome measures
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

Overall study start date
01/02/2004

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

Age group
Adult

Sex
Both

Target number of participants
700

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)

Sponsor details
Brigantia Building
Penrallt Road
Bangor
Wales
United Kingdom
LL57 2AS

Sponsor type
University/education

Website
http://www.bangor.ac.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, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Results article	results	01/09/2013		Yes	No
Plain English results			20/01/2022	No	Yes