ISRCTN60280514 https://doi.org/10.1186/ISRCTN60280514

Neoadjuvant and adjuvant chemotherapy vs. neoa

Submission date 18/02/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 18/02/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 15/05/2025	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-chemotherapy-before-and-after-surgery-with-chemoradiation-before-surgery-for-cancer-food-pipe-neo-aegis

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2011-001858-28

ClinicalTrials.gov (NCT)
NCT01726452

Protocol serial number
CPMS 18094

Study information

Scientific Title
Neo-AEGIS (NEO-adjuvant trial in Adenocarcinoma of the oEsophagus and oesophagoGastric junction International Study): Randomised Clinical Trial of neoadjuvant and adjuvant chemotherapy (Investigator's choice of Modified MAGIC or FLOT regimen) versus neoadjuvant chemoradiation (CROSS protocol) in adenocarcinoma of the oesophagus and oesophago-gastric junction

Acronym
Neo-AEGIS

Study objectives
The primary objective is to compare two level-1 evidence based approaches to adenocarcinoma of the oesophagus and oesophago-gastric junction. The MAGIC study included a minority of patients with oesophageal and junctional tumours and staging and QA modalities did not encompass current standards. The CROSS trial was not specific to adenocarcinoma, and compared a multimodal regimen to surgery alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands – Leicester, 18/12/2014, ref: 14/EM/1284

Study design
Randomized; Interventional; Design type: Process of Care, Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adenocarcinoma of the oesophagus and oesophago-gastric junction

Interventions
1. Chemotherapy: ECX/ECF or EOX/EOF v Paclitaxel/Carboplatin given concurrently with radiotherapy
2. Radiotherapy: Concurrently with paclitaxel/carboplatin chemotherapy pre-surgery
3. Surgery: Following neoadjuvant treatment

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
To evaluate 1, 2 and 3 year survival of patients treated with resection plus neoadjuvant and adjuvant chemotherapy, versus resection plus neoadjuvant chemo radiotherapy.

Key secondary outcome(s))
To evaluate the effect of both neoadjuvant regimens on clinical and pathological response rate, tumour regression grade, surgical resection rate, node-positivity, post-operative pathology, disease-free survival and time to treatment failure.

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Histologically verified adenocarcinoma of the oesophagus or oesophagogastric junction based on OGD
2. CT- 18FDG-PET in all patients and EUS, if feasible
3. Staging laparoscopy will be performed for tumours of the abdominal oesophagus, junction and

proximal stomach i.e. AEG II and AEG III (at the investigator's discretion)
4. Pre-treatment stage cT2-3, N0-3, M0
5. No prior abdominal or thoracic radiotherapy
6. Male/female patients aged >18 years
7. ECOG Performance Status 0, 1 or 2
8. ASA Grading I-II
9. Adequate cardiac function. For patients with a significant cardiac history (e.
g. known ischaemic disease, cardiomyopathy) an ejection fraction >50% and cardiac clearance by a consultant cardiologist for major surgery and cancer therapies is required, if clinically indicated

Where necessary, the Chief Investigator should be consulted to discuss the patient's eligibility.
10. Adequate respiratory function. Patients should have pulmonary function tests completed with

11.Adequate bone marrow function: absolute neutrophil count (ANC) >1.5x109 /l; white blood cell count >3x109/l; platelets > 100x109/l; haemoglobin (Hb) >9g/dl (can be post-transfusion).
12.Adequate renal function: glomerular filtration rate >60ml /minute calculated using the Cockcroft-Gault Formula
13.Adequate liver function: serum bilirubin <1.5x ULN; AST <2.5x ULN and ALP <3x ULN (ULN as per institutional standard)
14. Written informed consent must be obtained from the patient before any study specific procedures are performed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
377

Key exclusion criteria
1. Tumours of squamous histology
2. Patients with advanced inoperable or metastatic oesophageal, junctional or gastric adenocarcinc

3. Any prior chemotherapy for gastrointestinal cancer
4. Prior abdominal or thoracic radiation
5. Patients who are unfit for surgery or cancer treatments based on cardiac disease
6. Clinical COPD with significant obstructive airways disease classified by FEV1 < 1.5 L or PaO2 less

7. Known peripheral neuropathy >Grade 1 (absence of deep tendon reflexes as the sole neurologic

8. Known positive tests for human immunodeficiency virus (HIV) infection, acute or chronic active h

9. Any other malignancies within the last 5 years (other than curatively treated basal cell carcinoma

Date of first enrolment
02/03/2015

Date of final enrolment
23/12/2020

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Study participating centre
Royal Surrey County Hospital (lead site)
Egerton Road
Guildford
Surrey
United Kingdom
GU2 7XX

Study participating centre
Queen Elizabeth Medical Centre
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
Bristol Haematology and Oncology Centre
Horfield Road
Bristol
United Kingdom
BS2 8ED

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle Upon Tyne
Tyne and Wear
United Kingdom
NE7 7DN

Study participating centre
Royal Infirmary of Edinburgh
51 Little France Crescent
Edinburgh
United Kingdom
EH16 4SA

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Oxford Cancer and Haematology Centre
Churchill Hospital

Old Road
Headington
Oxford
United Kingdom
OX3 7LE

Study participating centre
St Mary's Hospital
Praed Street
Paddington
London
United Kingdom
W2 1NY

Study participating centre
Royal Preston Hospital
Sharoe Green Lane North
Fulwood
Preston
United Kingdom
PR2 9HT

Study participating centre
Beatson West of Scotland Cancer Centre
1053 Great Western Road
Glasgow
United Kingdom
G12 0YN

Study participating centre
Clatterbridge Cancer Centre
85 Pembroke Place
Liverpool
United Kingdom
L7 8YA

Study participating centre
Castle Road Hospital
Hull University Teaching Hospitals NHS Trust
Castle Road
Cottingham

Hull
United Kingdom
HU16 5JQ

Study participating centre
Nottingham City Hospital
Nottingham University Hospitals
City Hospital Campus
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Mount Vernon Cancer Centre
East and North Hertfordshire NHS Trust
Rickmansworth Road
Northwood
United Kingdom
HA6 2RN

Study participating centre
University Hospitals Coventry and Warwickshire
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Velindre Cancer Centre
Velindre Road
Whitchurch
Cardiff
United Kingdom
CF14 2TL

Study participating centre
Queen Alexandra Hospital
Portsmouth Hospitals NHS Trust
Southwick Hill Road
Portsmouth

United Kingdom
PO6 3LY

Study participating centre
Belfast City Hospital
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Study participating centre
Worcestershire Acute Hospitals NHS Trust
Woodrow Drive
Redditch
United Kingdom
B98 7UB

Sponsor information

Organisation
Cancer Trials Ireland

ROR
https://ror.org/01dpkyq75

Funder(s)

Funder type
Government

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Trial data are provided to the Neo-AEGIS DSMB and will be used in trial publications, however individual patient data will not be provided to external groups on request. The trial data are held at the HRB Clinical Research Facility in Galway, Ireland: http://www.nuigalway.ie/hrb_crfg/

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		18/09/2023	15/01/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results		12/05/2025	15/05/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes