# Neoadjuvant and adjuvant chemotherapy vs. neoa

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

# 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

Dr Neo-AEGIS Coordinator

#### Contact details

Clinical Trials Unit, MP 131, Tremona Road Southampton United Kingdom SO16 6YD

neoaegis@soton.ac.uk

# 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 adenocarcing
- 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 **Oueen 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

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
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