# Impact of chemotherapy on fitness before surgery on patients with cancer of oesophagus and stomach

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
27/02/2017		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/03/2017	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
24/01/2020	Cancer			

## Plain English summary of protocol

Background and study aims:

Surgical resection remains the best chance of cure for patients with cancer of the stomach of oesophagus (food pipe). There is a 30% chance of death associated with this type of surgery, with heart complications responsible for a large number of patients who die after surgery. Complications have a negative impact on survival and quality of life after surgery. Neoadjuvant chemotherapy (anti-cancer medications given before surgery to help shrink the tumour) is now common practice. The best time to undertake surgical procedures after neoadjuvant therapy in cancer of the stomach of oesophagus is not well defined. The aim of this study is to look at the effects of neoadjuvant chemotherapy on physical fitness and health in patients with this type of cancer.

## Who can participate?

Adults who have been diagnosed with cancer of the oesophagus or stomach who are suitable for neoadjuvant chemotherapy before surgery.

#### What does the study involve?

Participants have routine clinical data collected before starting their treatment. Following three cycles of neoadjuvant chemotherapy delivered as part of normal care, further tests are completed to assess the effects of the treatment. This involves having samples taken for testing, completing questionnaires and undergoing body scans and assessments.

What are the possible benefits and risks of participating? There are no direct benefits or risks involved with participating.

Where is the study run from? Royal Victoria Infirmary (UK)

When is study starting and how long is it expected to run for? October 2015 to October 2017 Who is funding the study? Northern Oesphagogastric Cancer Fund (UK)

Who is the main contact? Dr Maziar Navidi

## Contact information

## Type(s)

Scientific

#### Contact name

Dr Maziar Navidi

#### Contact details

Northern Oesophagogastric Unit Royal Victoria Infirmary Queen Victoria Road Newcastle upon Tyne United Kingdom NE2 1JQ

## Additional identifiers

**EudraCT/CTIS** number

#### **IRAS** number

172690

ClinicalTrials.gov number

## Secondary identifying numbers

IRAS Project ID 172690

# Study information

#### Scientific Title

Impact of neo-adjuvant chemotherapy on cardiorespiratory reserve in oesophago-gastric carcinoma

## **Study objectives**

The aim of this feasibility study is to investigate the effects of neoadjuvant chemotherapy on physical fitness and health in patients with oesophagogastric adenocarcinoma.

#### Study objectives:

- 1. Optimise the timing of surgery
- 2. Identify variables that could improve maintenance of fitness and health during chemotherapy
- 3. Reduce negative impact of chemotherapy
- 4. Inform future studies in this area

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

NRES Committee North East - Newcastle & North Tyneside 2, 09/09/2015, ref: 15/NE/0276

## Study design

Observational longitudinal study

## Primary study design

Observational

## Secondary study design

Longitudinal study

## Study setting(s)

Hospital

## Study type(s)

Diagnostic

## Participant information sheet

Not available in web format, please use the contact details below to request a patint information sheet'. navidi@doctors.org.uk

## Health condition(s) or problem(s) studied

Adenocarcinoma of oesophagus or stomach

#### **Interventions**

Eligible patients for the study are identified at MDM and are approached at the next available oncology clinic at which point an Information leaflet is disseminated to interested patients. Twenty four hours is given before written informed consent is obtained. Recruited patients respective GPs are informed. Routine pre operative data (patient characteristics which are collected in all patients routinely) and CPET data (this is standard of care for all patients and forms part of pre assessment) are added to research data base. Base line questionnaires as well as Grip Test and TGUG performed (study data) are collected as part of the research study. Attempted three cycles of NAC completed (standard of care). Toxicity data collected (standard of care). Each chemotherapy cycle lasts 21 days. First post NAC set of data collected (CPET; Grip Test; TGUG as well as questionnaires) (study data collected as part of the study and anonymised) this is performed at 0-7 days post completion of NAC.

Second post NAC set of data is collected at 14-21 days post completion of NAC (CPET; Grip Test; TGUG as well as questionnaires) (study data collected as part of the study and anonymised). Third post NAC set of data is collected at 28-35 days post completion of NAC (CPET; Grip Test; TGUG as well as questionnaires) (study data collected as part of the study and anonymised). The proposed surgical intervention is then carried out. The clinical team are blinded to the outcome of the study.

#### Intervention Type

Procedure/Surgery

## Primary outcome measure

Effect of net-adjuvant chemotherapy on cardiorespiratory fitness in patients with oesophagogastric adenocarcinoma is measured using Cardiopulmonary Exercise Testing (CPET) immediately following chemotherapy (baseline) and before surgery (at 0 weeks, 2 weeks and 4 weeks)

## Secondary outcome measures

- 1. Objective measurement of changes and restoration of fitness after chemotherapy in order to optimise timing of surgery
- 2. Impact of NAC on quality of life indices using The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) in combination with Oesophago-gastric Questionnaire (EORTC QLQ-OG25) before chemotherapy at 0 weeks post chemotherapy and at 4 weeks post chemotherapy prior to surgery
- 3. Impact of NAC on nutritional status is measured using the Mini Nutritional Assessment questionnaire (MNA) before chemotherapy at 0 weeks post chemotherapy and at 4 weeks post chemotherapy prior to surgery
- 4. Impact of NAC on sarcopenia is assessed by measuring the following:
- 4.1. Muscle mass is measured using CT scans pre and post chemotherapy performed as part of routine clinical care
- 4.2. Muscle strength Grip strength is measured using a hydraulic hand dynameter before chemotherapy at 0 weeks post chemotherapy and at 4 weeks post chemotherapy prior to surgery
- 4.3. Muscle Function is measured using the Timed Get up and Go test (TGUG) before chemotherapy at 0 weeks post chemotherapy and at 4 weeks post chemotherapy prior to surgery

## Overall study start date

01/10/2015

## Completion date

01/10/2017

# Eligibility

## Key inclusion criteria

- 1. Histological diagnosis of adenocarcinoma of the oesophagus or stomach
- 2. Patients deemed suitable for neo-adjuvant chemotherapy prior to resectional surgery
- 3. Absolute or relative contraindication in the patient's ability to perform serial (cardiopulmonary exercise tests) CPETs
- 4. Written informed consent
- 5. Aged 18 years and over

## Participant type(s)

Patient

## Age group

Adult

## Lower age limit

18 Years

#### Sex

Both

## Target number of participants

30

#### Total final enrolment

31

#### Key exclusion criteria

- 1. A pathological diagnosis other than adenocarcinoma.
- 2. Inability to consent or withdrawal of consent at any point during the research process
- 3. Absolute or relative contraindication to CPET testing:
- 3.1. Absolute:
- 3.1.1. Acute myocardial infarction (3–5 days)
- 3.1.2. Unstable angina
- 3.1.3. Uncontrolled arrhythmias causing symptoms or haemodynamic compromise
- 3.1.4. Syncope
- 3.1.5. Active endocarditis
- 3.1.6. Acute myocarditis or pericarditis
- 3.1.7. Symptomatic severe aortic stenosis
- 3.1.8. Uncontrolled heart failure
- 3.1.9. Acute pulmonary embolus or pulmonary infarction
- 3.1.10. Thrombosis of lower extremities
- 3.1.11. Suspected dissecting aneurysm
- 3.1.12. Uncontrolled asthma
- 3.1.13. Pulmonary oedema
- 3.1.14. Room air desaturation at rest 85%\*
- 3.1.15. Respiratory failure
- 3.1.16. Acute noncardiopulmonary disorder that may affect exercise performance or be aggravated by exercise (ie, infection, renal failure, thyrotoxicosis)
- 3.1.17. Mental impairment leading to inability to cooperate
- 3.2. Relative:
- 3.2.1. Left main coronary stenosis or its equivalent
- 3.2.2. Moderate stenotic valvular heart disease
- 3.2.3. Severe untreated arterial hypertension at rest or haemodynamic compromise (>200 mm Hg systolic, >120 mm Hg diastolic)
- 3.2.4. Tachyarrhythmias or bradyarrhythmias
- 3.2.5. Highdegree atrioventricular block
- 3.2.6. Hypertrophic cardiomyopathy
- 3.2.7. Significant pulmonary hypertension
- 3.2.8. Advanced or complicated pregnancy
- 3.2.9. Electrolyte abnormalities
- 3.2.10. Orthopaedic impairment that compromises exercise performance

#### Date of first enrolment

01/11/2015

#### Date of final enrolment

04/10/2016

## **Locations**

#### Countries of recruitment

England

**United Kingdom** 

## Study participating centre Royal Victoria Infirmary

Northern Oesophagogastric Unit, Queen Victoria Road Newcastle upon Tyne United Kingdom NE1 4LP

# Sponsor information

## Organisation

Royal Victoria Infirmary

## Sponsor details

Newcastle upon Tyne Newcastle upon Tyne United Kingdom NE1 4LP

## Sponsor type

Charity

#### Website

http://www.newcastle-hospitals.org.uk/hospitals/royal-victoria-infirmary.aspx

#### **ROR**

https://ror.org/01p19k166

# Funder(s)

## Funder type

Charity

#### **Funder Name**

Northern Oesphagogastric Cancer Fund

## **Results and Publications**

## Publication and dissemination plan

Planned publication in a high-impact peer reviewed journal.

## Intention to publish date

10/10/2017

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Maziar Navidi (Navidi@doctors.org.uk)

## IPD sharing plan summary

Available on request

## **Study outputs**

Output type	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2018	24/01/2020	Yes	No
HRA research summary			28/06/2023	No	No