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

Submission date
27/02/2017

Recruitment status
No longer recruiting

Registration date
08/03/2017

Overall study status
Completed

Last Edited
24/01/2020

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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