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Body composition, nutrition & outcomes after neoadjuvant chemotherapy

Submission date	Recruitment status	[ ] Prospectively registered
13/03/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/03/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
20/04/2016	Cancer	[ ] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-body-changes-during-chemotherapy-and-nutitional-support-for-people-having-treatment-for-stomach-or-oesophageal-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

11565

Study information

Scientific Title
The effects of an intensive nutritional support programme on body composition, insulin resistance and outcomes during neoadjuvant chemotherapy for oesophagogastric cancer: A before and after pilot study

Study objectives
Oesophageal and gastric cancer together represent the third most common cause of cancer death in the UK. The prognosis is often poor with overall UK 5-year survival rates being approximately 8% and 14% for oesophageal and stomach cancer, respectively. The majority of patients present with advanced disease and many have significant co-morbidities. Patients presenting with locally advanced resectable disease typically undergo 3 cycles of neoadjuvant chemotherapy (NAC) over 2 months followed by surgery, a regimen based on the MAGIC trial, which leads to down-staging of tumours and significantly improves progression-free and overall survival.

Whilst nutritional depletion is commonly encountered in patients with oesophagogastric (OG) cancers, most patients undergoing NAC do not receive nutritional support. Furthermore, there are limited data on preoperative nutritional support of patients with OG cancer undergoing NAC, the majority of previous studies utilising parenteral nutrition, which is expensive, invasive and carries risks of infectious morbidity.

This pilot study aims to investigate:
1.The development of sarcopenia (loss of FFM) in patients with OG cancer undergoing NAC increases chemotherapy-related toxicity, limits treatment and influences oncological outcome
2. Loss of FFM (muscle) leads to an increase in insulin resistance and associated post operative complications
3. An intensive nutritional support programme (INSP) during NAC can reverse the loss of FFM and the development of insulin resistance and whether this affects clinical outcomes

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 11/EM/0419

Study design
Non-randomised interventional prevention trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Upper Gastro-Intestinal Cancer; Oesophagus, Stomach

Interventions
INSP, Intensive Nutritional Support Programme
Early dietetic assessment and interventions as deemed neccessary to maintain nutritional requirments

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Changes in insulin sensitivity correlated with changes in lean body mass measured at the end of study

Secondary outcome measures
1. Incidence of chemotherapy toxicity and chemotherapy completion rates
2. Inflammatory cytokine concentrations
3. Insulin sensitivity measured
4. Muscle gene and protein expression
5. Pathological tumour response rates
6. Postoperative infectious and non-infectious complications
7. Respiratory muscle function
Measured at the end of the study

Overall study start date
20/02/2012

Completion date
20/02/2013

Eligibility

Key inclusion criteria
1. Age 18 - 80 years
2. Confirmed oesophageal or gastric (adenocarcinoma or squamous cell) carcinoma in patients due to undergo neoadjuvant chemotherapy
3. Able to give informed consent and comply with study protocol

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Key exclusion criteria
1. Patients with GIST tumours
2. Presence of severe organ specific disease (e.g. heart/respiratory/renal/liver failure)
3. Presence of inherited metabolic disorders
4. Simultaneous participation in another clinical study
5. Patients with suspicion of alcohol/drug abuse
6. Diabetes mellitus or other endocrine disorders (e.g. thyroid disease, Cushings syndrome)

For second study cohort receiving INSP:
1. Allergy to any constituent of the nutritional supplements
2. Total dysphagia (inability to take oral liquids or solids)
3. Clinical evidence of aspiration

Date of first enrolment
20/02/2012

Date of final enrolment
20/02/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Nottingham
Nottingham
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Sponsor information

Organisation
University of Nottingham (UK)

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Research Innovation Services
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Sponsor type
University/education

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
Core - The Digestive Disorders Foundation (UK)

Funder Name
Nottingham University Hospitals Charity (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration