

Body composition, nutrition & outcomes after neoadjuvant chemotherapy

Submission date 13/03/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/03/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/04/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-body-changes-during-chemotherapy-and-nutritional-support-for-people-having-treatment-for-stomach-or-oesophageal-cancer>

Contact information

Type(s)

Scientific

Contact name

Prof Dileep Lobo

Contact details

University of Nottingham
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH
+44 115 823 1155
dileep.lobo@nottingham.ac.uk

Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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 necessary to maintain nutritional requirements

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

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

United Kingdom

England

Study participating centre

University of Nottingham

Nottingham

United Kingdom

NG7 2UH

Sponsor information

Organisation

University of Nottingham (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

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration