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Improving fitness after gullet cancer surgery: a pilot trial of the impact of rehabilitation on quality of life, physical fitness and nutrition following surgery for cancer of the gullet

Submission date
01/11/2021

Recruitment status
No longer recruiting

Registration date
02/11/2021

Overall study status
Completed

Last Edited
27/06/2025

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-returning-to-normal-activities-after-surgery-for-oesophageal-cancer-faro

Background and study aims
Oesophageal (gullet) cancer is associated with a poor prognosis. Optimal treatment involves surgery and chemo(radio)therapy and is complex. Patients receive no help to improve and restore their quality of life and physical fitness after surgery for oesophageal cancer. Rehabilitation describes methods to help restore patients to their normal levels of activity. Little is known of the impact of rehabilitation upon the quality of life (wellbeing) among patients who have had an operation for oesophageal cancer.
The FARO study is a pilot trial to determine if a rehabilitation programme can improve the quality of life of patients that have had oesophageal (gullet) cancer surgery.

Who can participate?
Adults over 18 years, undergoing a curative trans-thoracic oesophagectomy for cancer.

What does the study involve?
Sixty adult patients will participate in the study from one centre in the United Kingdom (Northern Oesophagogastric Unit, Newcastle Upon Tyne) and will be divided into two groups: 30 patients will receive standard care. 30 patients will participate in the rehabilitation programme in addition to routine care. Having two groups will help identify differences in quality of life after surgery with the addition of the programme.
A special computer programme will be used to help allocate patients to a group. This is to ensure that there are no external influences that can impact the decision of which group a patient should be allocated to, thereby making the study as fair as possible.
Following surgery for oesophageal cancer, patients will have their baseline quality of life, physical fitness (including step-count) and dietary markers assessed.

Patients undergoing gullet cancer surgery will be reviewed at:
1. 2 weeks post-discharge
2. 6 weeks post-discharge
3. 3- and 6 months post-surgery

No change will be made in this pathway for the purpose of this study.

Those patients randomised to the intervention arm will:
1. Complete a walking exercise regime with target daily step-count
2. Undertake strengthening exercises (three times a week week)
3. Measure daily activity and step-count using an activity tracker
4. Record fatigue levels and post-operative symptoms in a study diary (provided)
Patients' quality of life, strength, physical fitness and diet will be assessed 6 weeks after going home from hospital following their operation and at 3 and 6 months thereafter, to coincide with routine follow-up, using questionnaires. The programme lasts for 12 weeks.

What are the possible benefits and risks of participating?
Possible benefit(s) to patients randomised to complete rehabilitative interventions include:
1. Improved quality of life after gullet cancer surgery
2. Swifter recovery of physical function
3. Improved nutrition
4. Improved overall survivorship
Patients randomised to receive standard care may be motivated to engage in increased physical activity following their surgery to improve their fitness, although they will not receive the prescribed interventions.
We do not anticipate any risks to patients, as a result of participation.

Where is the study run from?
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
September 2021 to March 2024

Who is funding the study?
Newcastle Hospitals Charity (UK)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
277338

Central Portfolio Management System (CPMS)
50359

Study information

Scientific Title
Fitness AfteR Oesophagectomy - an external pilot trial of the impact of rehabilitation on quality of life after surgery for oesophageal cancer

Acronym
FARO

Study objectives
Patients who have undergone surgery for oesophageal cancer have better quality of life and physical fitness with focussed rehabilitative interventions compared to patients receiving routine clinical care alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/09/2021, HRA Health and Care Research Wales (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)1792 606334; Wales.REC2@wales.nhs.uk), ref: 21/WA/0288

Primary study design
Interventional

Study design
Single-centre interventional open-label pilot randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Oesophageal cancer

Interventions
Sixty patients will be recruited into the study from one centre (Northern Oesophagogastric Unit, Royal Victoria Infirmary, Newcastle Upon Tyne), with 30 patients in each group.

The rehabilitation programme runs over 12 weeks. Patients assigned to receive rehabilitation will start the programme within 3 weeks of discharge from hospital.

STANDARD POST-OPERATIVE CARE
Patients undergoing gullet cancer surgery at the host-site receive standard post-operative care across sites, with reviews at:
1. 2 weeks post-discharge
2. 6 weeks post-discharge
3. 3- and 6 months post-surgery

No change will be made in this pathway for the purpose of this study.

REHABILITATION PROGRAMME
Patients who are randomly assigned to receive rehabilitation will participate in the programme. They will:
1. Complete a walking exercise regime with target daily step-count
2. Undertake strengthening exercises (three times a week week)
3. Measure daily activity and step-count using an activity tracker
4. Record fatigue levels and post-operative symptoms in a study diary (provided)

In-hospital baseline assessments (outlined further) will determine initial daily step-count target. This will be agreed between the patient and research team.

Patients will receive a weekly phone call from a member of the research team during the 12-week programme. This will begin at the end of the first week of participation. During this call, the team will review:

1. Activity levels and daily step-count.
2. Compliance with taught exercises.
3. Fatigue and post-operative symptoms (discussed below)
4. Nutritional status (fortnightly) with a specialist dietitian

Weekly step-counts will be increased by 250-500 steps based on ability and clinical status. No change will be made should patients feel this is not achievable. Patients will be encouraged to increase targets until they subjectively feel pre-operative activity levels have been achieved.

Intervention Type
Behavioural

Primary outcome(s)
Quality of life measured using European Organisation For Research and Treatment of Cancer (EORTC) QLQ-C30 and OG-25 questionnaires at 6 weeks post-discharge from hospital (after oesophagectomy); 3- and 6 months post-oesophagectomy

Key secondary outcome(s)
1. Physical fitness- measured using the 6-minute walking test at 6 weeks post-hospital discharge and 3- and 6 months post-oesophagectomy.
2. Post-operative physical activity levels- measured by an activity tracker and patient-recorded study diary at 6 weeks post-hospital discharge and 3- and 6 months post-oesophagectomy.
3. Functional impact of sarcopenia (generalised loss of muscle mass and strength) - measured by hand-grip strength at 6 weeks post-hospital discharge and 3- and 6 months post-oesophagectomy.
4. Recruitment rate- measured by the proportion of eligible patients successfully recruited at the end of the study period.
5. Individual compliance- measured by activity tracker and concordance with study diary during the 6-month patient enrollment.
6. Effects of dietary counselling- measured by changes in micronutrient levels on blood tests and weight at 6 weeks post-hospital discharge and 3- and 6 months post-oesophagectomy.

Completion date
20/03/2024

Eligibility

Key inclusion criteria
1. Any patient undergoing a curative trans-thoracic oesophagectomy for malignancy. This includes open or minimally invasive or robotic Ivor Lewis oesophagectomy and three-stage three-field oesophagectomy with cervical anastomoses.
2. Age 18 years or over
3. Ability to provide consent to participation.
4. Ability to be able to complete planned interventions within the programme.
5. Any patient undergoing an oesophagectomy for cancer

Patients who have or due to undergo neoadjuvant or adjuvant chemotherapy will be included in the study, provided they meet the above inclusion criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
60

Key exclusion criteria
1. Absolute and relative contraindications to the 6-minute walk test, as defined by the American Thoracic Society.
2. Orthopaedic limitations to participating in the study intervention (daily walking and/or daily exercise), for example severe hip or knee disease such as osteoarthritis; lower limb amputation.
3. Post-operative complications precluding participation, for example- neutropenic sepsis with prolonged hospital admission during a cycle of adjuvant chemotherapy- such that the patient cannot commence the programme within 12 weeks of having their surgery.
4. Prolonged post-operative recovery that prevents commencing participation in study within 12 weeks of having their surgery.
5. Oesophago-gastrectomy with colonic interposition.
6. Patients with concurrent malignancies requiring surgical treatment (e.g.: breast) or radio /chemotherapy or immunotherapy (e.g.: haematological malignancies)

Date of first enrolment
18/10/2021

Date of final enrolment
14/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Victoria Infirmary
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NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Newcastle Hospitals Charity

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol (preprint)		04/10/2023	27/06/2025	No	No