ISRCTN83283595 https://doi.org/10.1186/ISRCTN83283595

Feasibility of a novel nutritional supplement for surgical patients

Submission date
16/05/2023

Recruitment status
No longer recruiting

Registration date
17/05/2023

Overall study status
Completed

Last Edited
13/08/2025

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
The feasibility study is designed to identify whether older surgical patients undergoing surgical intervention for abdominal complaints can take a small volume nutritional supplement consisting of essential amino acids with carbohydrate, and whether this supplementation can be sustained over a period of 4 weeks alongside their usual meals without any detrimental impact on appetite.

Who can participate?
Patients over the age of 60 years who are undergoing abdominal surgery either pre-operatively or postoperatively including postoperative elective and emergency patients.

What does the study involve?
The study involves tasting a nutritional supplement and then taking the supplement over a four week period, twice daily. For the preoperative patients we will also assess the impact of the supplement on appetite by measuring appetite using a visual scale whilst eating a breakfast meal.

What are the possible benefits and risks of participating?
This study will help us learn about if these supplements can be tolerated for a period of time and any impacts on a patient you recover from your surgery. This is a safe study, but some parts may feel more difficult to do such as being asked to recall dietary intake relies on memory and may cause frustration and being asked to complete questionnaires may also cause frustration and survey fatigue.

Where is the study run from?
The research is sponsored by The University of Leeds where the researcher is a PhD candidate at The School of Medicine. The testing of participants will be at St. James's University Hospital, Leeds Teaching Hospitals Trust and Carnegie School of Sport, Headingley Campus, Leeds Beckett University.

When is the study starting and how long is it expected to run for?
January 2020 to March 2024

Who is funding the study?
The University of Huddersfield (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
280595

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 280595

Study information

Scientific Title
Investigating the acceptability and feasibility of a novel nutritional supplement on patients undergoing different treatment stages for cancer and emergency disease presentations

Study objectives
The research team aim to investigate the feasibility and acceptability of novel nutritional supplementation in bowel cancer patients preoperatively and patients who have emergency bowel surgery or planned colorectal cancer surgery postoperatively.
The project will be conducted in two parts: part A and part B. In part A of the feasibility study the key research question the research team will aim to answer is:
“Does consumption of a nutritional gel (65 ml) before an 'ad libitum' breakfast (eat as much as someone can eat) negatively affect appetite and energy intake compared to a breakfast alone (control)?”
The key outcomes measured will be nutritional intakes, appetite and palatability perceptions at the breakfast.
In part B of the feasibility study the key research question the research team will aim to answer is:
“Can participants (who also completed part A) consume two supplements daily over a longer period of time without compromising their ability to eat food?”
The key outcomes measured will be habitual nutritional intakes and monitoring compliance to the supplementation regime.
A secondary question for participants in part B will be:
“Can short-term supplementation improve body composition and aspects of physical fitness?”

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/03/2021, Yorkshire and the Humber – South Yorkshire Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 207 104 8121; southyorks.rec@hra.nhs.uk), ref:21/YH/0054

Study design
Feasibility study using a crossover design at a single centre

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)

Efficacy

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Sarcopenia in older abdominal surgical patients

Interventions
Following consent to proceed, all participants undertake a taste test (Part A) where participants record how the supplement tastes to them on a visual analogue scale. The preoperative patients (Group 1) visit Leeds Beckett University campus twice for appetite testing (Part A) where they consume an ad libitum breakfast meal on each occasion, recording their appetite on a visual analogue scale. On one of the two visits the participants will take the supplement alongside. The two visits will then compare effect of supplement on appetite in a crossover design. Postoperative participants (Group 2 & 3) do not undergo appetite testing as they are in hospital. Participants will then be given a 4-week regime of twice daily supplementation (Part B) and record a food diary over 3 days at week 3 to assess impact of supplement on macronutrient intake with supplementation.
(see outputs table below for a Flow Diagram illustrating this)

Physical assessment is performed on all patients before and after a period of supplementation, measuring handgrip strength using a dynamometer, body composition measurements using a bioelectrical impedance analyser and a timed get up and go test of 3 metres to assess baseline fitness.

Overall involvement is for 4-5 weeks.

Intervention Type
Supplement

Primary outcome measure
Part A:
1. Nutritional intake measured using calorie count and macronutrient analysis at each breakfast
2. Appetite assessment (Flint 2000) taken twice at each breakfast meal for the preoperative participants
3. Palatability perceptions measured using visual analogue scales to test palatability of the supplement at single time point

Part B, measured using patient interview at a single time point
1. Habitual nutritional intakes
2. Compliance with the supplementation regime

Secondary outcome measures
Part B, measured at a single time point:
1. Body composition: Fat mass and muscle mass as measured by a Tanita bioelectrical impedance analyser
2. Jagar dynamometer to measure grip strength
3. Timed get and go test of 3 metres to assess baseline fitness

Overall study start date

29/01/2020

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Group 1
1.1. Patient has colorectal cancer and is due for elective surgery for cancer
1.2. Patient is over 60 years of age

Group 2
2.1. Patient has colorectal cancer and had had elective surgery for cancer
2.2. Patient is over 60 years of age

Group 3
3.1. Patient has been admitted as an emergency and has had emergency surgical intervention for abdominal conditions.Patient is over 60 years of age.

All groups
4. Patient has capacity to understand the study and give informed consent
5. Patient is capable of ingesting the oral supplement

Participant type(s)
Patient

Age group
Adult

Lower age limit
60 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
18

Total final enrolment
22

Key exclusion criteria
1. Patient is incapable of understanding the study and giving informed consent
2. Patient is incapable of ingesting the oral supplement
3. Patients with the very rare potential complication of an allergy to nutritional supplement (sodium benzoate or sodium metabisulphites).

4. Preoperative patients (group 1) with pacemakers or similar electrical implants will be excluded as they will undergo bioelectrical impedance studies and this is a contraindication to using the analyser.

Date of first enrolment
06/08/2021

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
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Study participating centre
Leeds Beckett University
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Sponsor type
University/education

Website
https://ris.leeds.ac.uk/research-ethics-and-integrity/faculty-specific-information/medicine-and-health-faculty-research-ethics-committee-inc-four-school-recs/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
University of Huddersfield

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
It is anticipated that the findings will be disseminated through conference presentations and high-impact journal publication

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the study are currently 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?
Other files	Flow Diagram for Interventions		17/05/2023	No	No
Participant information sheet	Group 1 version 0.2	01/03/2021	17/05/2023	No	Yes
Participant information sheet	Groups 2 & 3 version 0.3	01/04/2021	17/05/2023	No	Yes
HRA research summary			28/06/2023	No	No
Other files			24/10/2024	No	No
Basic results			13/08/2025	No	No
Protocol file	version 0.1	30/11/2020	13/08/2025	No	No
Statistical Analysis Plan			13/08/2025	No	No