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Physical training and nutrition before abdominal surgery for Crohn's disease

Submission date
16/11/2021

Recruitment status
No longer recruiting

Registration date
16/11/2021

Overall study status
Completed

Last Edited
10/09/2024

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
Crohn's disease is a lifelong condition where parts of the digestive system become inflamed. People with Crohn's disease who require bowel surgery are at increased risks of problems after surgery as compared to people who have other bowel conditions. It is known that one reason for this increase in risk is that people with Crohn's disease often have a reduced amount of muscle, which impedes the body's ability to recover from surgery. The aim of this study is to find out whether prehabilitation can improve outcomes after bowel surgery in Crohn's disease. Prehabilitation means that the person performs an exercise programme 4 weeks before the operation. This has been effective in people in other age groups who have bowel surgery for other conditions.

Who can participate?
Patients aged 16 years or older who will undergo bowel surgery for Crohn's disease and who do not have any difficulties completing the 4-week prehabilitation programme.

What does the study involve?
Participants visit the hospital to undergo measurements of physical activity on four occasions: before and after the 4-week prehabilitation programme (or standard care), and 4 and 8 weeks after the operation. On these occasions, physical function is measured by simple tests such as walking for 6 minutes, sitting and standing from a chair, and arm curls. The muscle in the thigh is also measured using a scan. Questionnaires related to well-being are also filled in by the participant.
Participants are then randomly (by chance) allocated to one of two groups: the prehabilitation group and the standard treatment group. Participants in the prehabilitation group do supervised exercise five times per week for 4 weeks leading up to the operation. Once per week, they visit the hospital and do the exercise there. They also receive a protein supplement. Participants in the standard treatment group do not perform the supervised exercise programme and do not take extra protein supplements, but are treated in the usual way before bowel surgery. This involves 4 weeks of adjusting medications and addressing common health issues before surgery. The operation and care before and after surgery are not affected by participation in the study.

What are the possible benefits and risks of participating?
Potential benefits include improved physical function in the prehabilitation group, and increased testing beyond clinical routines in both groups. Potential risks in both study groups include musculoskeletal pain and pain from blood tests.

Where is the study run from?
Ersta Hospital (Sweden)

When is the study starting and how long is it expected to run for?
January 2020 to January 2026

Who is funding the study?
1. Stockholm Healthcare Region (Sweden)
2. The CJ och HR Hierta Memorial Foundation (Sweden)

Who is the main contact?
Dr Mattias Soop
forskningsenheten@erstadiakoni.se

Contact information

Type(s)
Scientific

Contact name
Dr Mattias Soop

ORCID ID
https://orcid.org/0000-0003-4287-6978

Contact details
Dept of Surgery
Ersta Hospital
Fjallgatan 44
Stockholm
Sweden
SE 116 28
+46 (0)8 714 6500
forskningsenheten@erstadiakoni.se

Type(s)
Public

Contact name
Ms Charlotte Jonsson

Contact details
Research Unit
Ersta Hospital
Fjallgatan 44
Stockholm

Sweden
SE 116 28
+46 (0)8 714 6500
forskningsenheten@erstadiakoni.se

Additional identifiers

Protocol serial number
213

Study information

Scientific Title
Prehabilitation in abdominal surgery for Crohn's disease: a randomised trial

Acronym
PASC

Study objectives
It is hypothesised that an intensive, supervised 4-week prehabilitation programme in people undergoing bowel resection for Crohn’s disease is feasible and results in an improvement in physical function from baseline to the week before surgery.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/08/2020, Etikprovningsmyndiheten (Swedish Ethical Review Authority) (Box 2110, Uppsala, SE 750 02, Sweden; +46 (0)10-4750800; registrator@etikprovning.se), ref: 2020-03436; amendment 2021-01680 (approved 19/04/2021)

Primary study design
Interventional

Study design
Interventional non-blinded randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Crohn's disease requiring abdominal surgery

Interventions
Randomisation 1:1 to prehabilitation or control treatment is based on a sequence of random numbers. The sequence will be stratified for study site (Stockholm and Montréal) and gender. The sequence will be concealed by opaque envelopes.

Prehabilitation entails endurance and resistance exercise and tailored protein supplementation. Participants will perform exercise five times per week for 4 weeks (20 occasions). Exercise is

performed in the hospital once a week and at home four times per week. On each training occasion, endurance exercise is performed for 32 minutes on a stationary exercise bicycle (in hospital) or by jogging or brisk walking (at home) to a Borg score of 13-15.

Resistance exercise is performed three times per week, and not on consecutive days. Two sets of 10 repetitions of elastic band loading and own bodyweight of six major muscle groups are performed: leg press, chest press, abdominal crunches floor, lateral pull-down, low row and step up. A target dietary protein intake of 1.5-1.8 g/kg bodyweight in all patients will be achieved by dietary advice and/or adding oral nutritional supplements to the baseline diet.

In addition, participants in the prehabilitation group will receive whey protein within 30 min following each exercise (5 days a week) and before sleep (7 days a week) at the following doses: 20 g (bodyweight less or equal to 50 kg), 30 g (bodyweight 51-80 kg) or 40 g (bodyweight 81 kg or more).

Participants randomised to the control group will receive current standard care during their preoperative period. They will not receive protein supplements.

Intervention Type
Mixed

Primary outcome(s)
Physical performance measured using the 6-minute walk test at baseline, after prehabilitation /control and 4 and 8 weeks after surgery

Key secondary outcome(s)
1. Physical performance measured using the timed stands test-30 at baseline, after prehabilitation/control and 4 and 8 weeks after surgery
2. Physical performance measured using handgrip strength at baseline, after prehabilitation /control and 4 and 8 weeks after surgery
3. Physical performance measured using the arm curl test-30 at baseline, after prehabilitation /control and 4 and 8 weeks after surgery
4. Dominant leg thigh muscle area using magnetic resonance imaging at baseline, after prehabilitation/control and 4 and 8 weeks after surgery
5. Patient-reported outcomes at baseline, after prehabilitation/control and 4 and 8 weeks after surgery:
5.1. General quality of life assessed using EuroQoL 5D-5L
5.2. Symptoms from Crohn's disease assessed using Harvey Bradshaw Index
5.3. Ability to do important daily activities assessed using Instrumental Activities of Daily Living (IADL)
6. Compliance with intervention measured by self-reported proportion of endurance and resistance exercises during the 20 daily exercises over the 4-week period before surgery
7. Total physical activity measured by a high-resolution activity tracker over the 4-week period before surgery
8. Postoperative length of stay measured using observation of the hospital stay at the duration of the stay after surgery (usually 2-10 days)
9. 30-day postoperative morbidity measured using patient record review at 30 days after surgery

Completion date
01/01/2026

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 10/09/2024:
1. Adults (aged ≥16 years)
2. Listed for elective or expedited (within weeks) small or large intestinal resection by laparoscopy or laparotomy for Crohn's disease
3. At Ersta Hospital, Stockholm

Previous participant inclusion criteria:
1. Adults (aged ≥16 years)
2. Listed for elective or expedited (within weeks) small or large intestinal resection by laparoscopy or laparotomy for Crohn's disease
3. At Ersta Hospital, Stockholm, and McGill University Health Centre, Montréal

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Key exclusion criteria
1. Inability to participate in the prehabilitation programme components
2. Operation performed through a peristomal incision alone

Date of first enrolment
01/01/2021

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
Sweden

Study participating centre
Ersta Hospital
Fjallgatan 44

Stockholm
Sweden
SE 116 28

Sponsor information

Organisation
Ersta sjukhus

ROR
https://ror.org/019tstz42

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Stockholm Healthcare Region

Funder Name
The CJ och HR Hierta Memorial Foundation

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?
Protocol file		16/11/2021	16/11/2021	No	No