Multimodal intensive prehabilitation in high impact surgery to reduce postoperative complications

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28368

Source
NTR

Brief title
F4S PREHAB trial

Health condition

colon cancer, rectal cancer, esophageal cancer, liver metastases from colorectal cancer, pancreato-biliary cancer, peritoneal carcinomatosis from colorectal cancer, retroperitoneal sarcoma, abdominal aortic aneurysm, renal cancer, bladder cancer, supratentorial meningioma, hip arthrosis, knee or hip arthroplasty failure, osteosarcoma, pulmonary cancer, thoracic aortic aneurysm, head and neck cancer, mouth cancer, breast reconstruction, ovarian cancer, endometrial cancer, vulvar cancer

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Radboudumc

Intervention

Outcome measures

Primary outcome

To determine the effects of a multimodal intensive prehabilitation program a high-risk patient group on complications (Clavien-Dindo score and Comprehensive Complication Index (CCI) score)

Secondary outcome

To investigate the effects of multimodal intensive personalized prehabilitation on an:
- Individual patient's level, i.e. length of hospital stay (in days), physical fitness (estimated VO2 peak, indirect 1 repetition measures, physical activity), nutritional status (body weight, fat-free mass), mental health (HRQoL), intervention adherence
- Mechanistic level, i.e. innate immune response (degree of immunoparalysis)
- Hospital-efficiency level: costs due to complications, costs due to length of hospital stay, budget impact, cost-effectiveness
- Macro-economic level: changes in patients volumes, shifts in care between 2nd and 1st line healthcare

Study description

Background summary

Rationale: High impact surgery has major consequences on the quality of life of patients. It takes them off normal work and life for prolonged periods and often they do not return to the preoperative level of daily activities and societal and work participation. Besides the regular impact of surgery, postoperative complications occur in up to 15-60% of patients and are associated with a higher mortality rate. The number and severity of complications is principally related to the initial quality of the surgical treatment. But also, it is strongly related to patients individual pre-operative functional capacity, pre-operative physical fitness, nutritional status, mental health, immune status and intoxications like alcohol abuse and smoking.
Complex operations are the core business of academic surgical departments and the whole peri-operative process (surgery, anesthesiology, intensive care treatment), as post-operative morbidity and handling of complications is intensive and costly. Traditional approaches have mainly focused on minimizing operative trauma (minimal invasive operations) and peri-operative clinical recovery programs, such as the Enhanced Recovery After Surgery (ERAS) protocol. Recent evidence, however, shows that the preoperative period might be the optimal time frame for intervention to achieve short term and long lasting effects. During the last years various so-called prehabilitation programs have been initiated with promising results. Prehabilitation, the optimization of a patient preoperatively, seems to prevent postoperative complications, enhance recovery after surgery and reduce cost of the burden of care. Therefore prehabilitation promises to be a straightforward intervention with a clear positive

intervention-outcome correlation from both patient's perspective and hospital's perspective. However, high levels of evidence lack, due to poor methodology and lack of a comprehensive approach of previous studies on the effect of prehabilitation. Moreover, the mechanistical effects of prehabilitation have not been explained so far and the effects on a macro-economic level are not clear.

Objective/study design: A stepped-wedge cluster randomized trial with a clear aim to demonstrate the effects on clinical outcomes, the underlying mechanistical effect and the cost efficiency of prehabilitation across a wide range of patients, diseases and procedures.

Study population: Adult patients undergoing elective high impact surgery for colon cancer, rectal cancer, esophageal cancer, liver metastases from colorectal cancer, pancreato-biliary cancer, peritoneal carcinomatosis from colorectal cancer, retroperitoneal sarcoma, abdominal aortic aneurysm, renal cancer, bladder cancer, supratentorial meningioma, hip arthrosis, knee or hip arthroplasty failure, osteosarcoma, pulmonary cancer, thoracic aortic aneurysm, head and neck cancer, mouth cancer, breast reconstruction, ovarian cancer, endometrial cancer, vulvar cancer will be included in this study.

Intervention: Patients will undergo a multimodal intensive prehabilitation program prior to high impact surgery including an exercise program, a nutritional intervention, psychological support and smoking cessation support.

Study objective

Undergoing a multimodal prehabilition program prior to high impact surgery will reduce postoperative outcomes

Study design

Surgical procedure -4 weeks or-8 weeks
- Screening (only in intervention group)
- Physical fitness and activity (submaximal Astrand test, indirect 1RM, SQUASH questionnaire)
- Nutritional status (length, body weight, fat-free mass, PG SGA SF)
- Health status (SF-36 questionnaire)

Surgical procedure -1 week
- Health behavior questionnaire
- Physical fitness and activity (steep ramp test, indirect 1RM)
- Nutritional status (length, body weight, fat-free mass, PG-SGA SF)
- QoL/efficiency (SF-36 questionnaire + iMCQ questionnaire)

Surgical procedure +1 month
- Postoperative complications
- Length of stay

Surgical procedure +3months
- QoL/efficiency (SF-36 questionnaire + iMCQ questionnaire)

Surgical procedure +6 months
- Physical activity (SQUASH questionnaire)
- QoL/efficiency (SF-36 questionnaire + iMCQ questionnaire + EQ-5D-5L questionnaire)

Surgical procedure +12 months
- Physical activity (SQUASH questionnaire)
- QoL/efficiency (SF-36 questionnaire + iMCQ questionnaire)

Intervention

Patients will undergo a multimodal intensive prehabilitation program prior to high impact surgery including an exercise program, a nutritional intervention, psychological support and smoking cessation support.

Contacts

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Eligibility criteria

Inclusion criteria

o Adult patients (>16 years),
o scheduled for elective high impact surgery,
o independent of (neo-) chemotherapy and/or radiotherapy,
o obtained written informed consent.

Exclusion criteria

o Paralytic or immobilized patients who are not able to complete exercise intervention,
o premorbid conditions or orthopedic impairments which contraindicate exercise,

o inability to undergo the intervention due to lack of understanding or instructability (e.g. cognitive disability or illiteracy (disability to read and understand Dutch)).
o unstable cardiac or respiratory disease which contraindicate exercise,
o renal failure stage 3 or higher which contraindicate protein supplementation
o ASA score 4 or higher,

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2021
Enrollment:	2830
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-06-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49362
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8699
CCMO	NL73777.091.20
OMON	NL-OMON49362

Study results