Multimodal intensive prehabilitation in high impact surgery to reduce postoperative complications

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28368

Bron
NTR

Verkorte titel
F4S PREHAB trial

Aandoening

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

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Radboudumc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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,

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2021
Aantal proefpersonen:	2830
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-06-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49362
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten