Better Be on Top

Gepubliceerd: 24-01-2020 Laatst bijgewerkt: 15-05-2024

As the incidence of colorectal cancer (CRC) is increasing with age and several surgical developments have been made the past few years, the number of older patients receiving surgical treatment is increasing. However, the impact of surgery should...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25416

Bron
NTR

Verkorte titel
BEBOP

Aandoening

Coloncancer or rectal cancer

Ondersteuning

Primaire sponsor: Reinier de Graaf Gasthuis
Overige ondersteuning: Team Westland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

One-year survival

Toelichting onderzoek

Achtergrond van het onderzoek

In this study, we will identify frailty in older colorectal cancer patients on six domains: physical performance, nutritional status, anemia, psychosocial, cognitive and smoking status. In case of frailty, patients will start with prehabilitation and rehabilitation to increase the preoperative and postoperative capacity and reduce the impact of surgery.

Doel van het onderzoek

As the incidence of colorectal cancer (CRC) is increasing with age and several surgical developments have been made the past few years, the number of older patients receiving surgical treatment is increasing. However, the impact of surgery should not be underestimated in the older CRC patients. Especially the frail older CRC patients have higher mortality and postoperative complication rates in comparison to the non-frail patients. Identifying and modifying vulnerabilities before and after surgery may increase the capacity and decrease the impact of surgery. Evidence of prehabilitation with or without the combination of rehabilitation is limited and inconsistent due to studies with small sample sizes and the inclusion of non-frail patients. This means that a large cohort study is needed to establish the effect of prehabilitation and rehabilitation in frail older CRC patients.

Onderzoeksopzet

Inclusion, baseline measurements, preoperative frailty evaluation, postoperative physcial test at 3, 6 and 12 months , postoperative evaluation of Qol and ADL at 6 and 12 months.

Onderzoeksproduct en/of interventie

Included patients will be screened for frailty on physical performance, nutritional status, anaemia, psychosocial, cognitive and smoking status. The physiotherapist will screen for physical frailty, the dietician for nutritional fraitly, the geriatrician for cognitive and psychosocial frailty and the surgeon for anaemia and smoking status. Only in case of frailty - defined by clear cut off points- interventions are initiated. Potential interventions are: four — six week exercise program, protein or energy supplements, iron infusion in case of proven iron deficiency anaemia, delirium preventing strategies, psychologic consultation and smoking cessation.

Contactpersonen

Publiek

Reinier de Graaf Gasthuis
Heleen van der Hulst

0152603830

Wetenschappelijk

Reinier de Graaf Gasthuis
Heleen van der Hulst

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- diagnosis of colorectal cancer
- 70 years or older
- non-metastatic disease
- planned for elective surgery
- positive geriatric screening based on the G8 or 6CIT

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Need for surgery in acute setting
- No need for surgery due to complete tumour remission after chemo-radiation in rectal cancer patients
- Not willing to provide informed consent
- Not able to perform an exercise program; for instance wheelchair-dependent patients or paraplegic patients
- Patients in whom an exercise program is contra-indicated due to severe cardiopulmonary problems, diagnosed by a cardiologist and/or pulmonologist (for example COPD gold IV,unstable coronary artery disease, heart failure or poorly controlled arrhythmias).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2020
Aantal proefpersonen:	310
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52663
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8321
CCMO	NL72163.058.19
OMON	NL-OMON52663

Resultaten