Pelvic Floor rehabilitation to improve functional Outcome and quality of life after surgery for Rectal CancEr: a randomized trial.

Gepubliceerd: 03-07-2015 Laatst bijgewerkt: 18-08-2022

Improving functional outcomes in rectal cancer surgery by a pelvic floor rehabilitation program.

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

Samenvatting

ID

NL-OMON27444

Bron
Nationaal Trial Register

Verkorte titel
FORCE-trial

Aandoening

Rectal cancer; pelvic floor rehabilitation (PFR); fecal incontinence, Low Anterior Resection Syndrome (LARS), low anterior resection, TME.

Ondersteuning

Primaire sponsor: UMCG, MCL, Isala Kliniek Zwolle
Other institutions invited
Overige ondersteuning: currently under review

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Wexner-score
- Fecal Incontinence Quality of Life score (FIQL)

Toelichting onderzoek

Achtergrond van het onderzoek

It is widely accepted that 90% of patients undergoing sphincter-preserving rectal surgery, will subsequently have a change in bowel habit, ranging from increased bowel frequency to fecal incontinence or evacuatory dysfunction. A two-armed randomized controlled trial will be conducted in patients who underwent sphincter-preserving rectal cancer surgery. This trial aimed to evaluate the incremental effect of PFR on the functional outcomes in patients after sphincter-preserving rectal cancer surgery. Patients will be randomized for standardized PFR or regular treatment. The study will be a multicenter trial in several tertiary referral centers and teaching hospitals. 56 patients will be included in each arm of the protocol. The total number of 112 patients will be included during an 18 month period and a minimal follow-up time of 1 year is necessary.

Doel van het onderzoek

Improving functional outcomes in rectal cancer surgery by a pelvic floor rehabilitation program.

Onderzoeksopzet

- Preoperative questionnaires

- Postoperative questionnaires and start of PFR 3 months after surgery (T0)

- 12 therapy sessions during 3 months

- Questionnaires after 3 months of PFR (T1)

- Questionnaires 12 months after start PFR (T2)

Onderzoeksproduct en/of interventie

Pelvic floor rehabilitation after low anterior resection for rectal cancer, including pelvic floor muscle training, biofeedback, electrostimulation and rectal balloon training.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients undergoing a low anterior resection for rectal cancer.

- Age over 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- No informed consent.

- Certain comorbidities: proctitis, colitis ulcerosa, Crohn's disease

- Necessity for resection beyond TME, ie T4 tumor.

- Previous course of pelvis radiotherapie, for other reasons then the current rectal carcinoma.

- Pelvic floor rehabilitation therapy in the last six months prior to rectal resection.

- Life expectancy less than 1 year.

- Mental or physical condition, that compromises the feasibility of the intervention.

- Not mastering the Dutch language.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	112
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5368
NTR-old	NTR5469
Ander register	: 80-84300-98-72021

Resultaten

Samenvatting resultaten
Wilhelmina S Visser, Wouter W te Riele, Djamila Boerma, Bert van Ramshorst, Henderik L van Westreenen. Pelvic Floor Rehabilitation to Improve Functional Outcome After a Low Anterior Resection: A Systematic Review. Annals of Coloproctology 2014; 30(3):109-114.