EMG evaluation of the Pelvic Floor and Functional Outcomes in patients who underwent Rectal Cancer Treatment

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

Samenvatting

ID

NL-OMON23744

Bron
NTR

Verkorte titel
EFFORT trial

Aandoening

Patients after Low anterior resection and/or (chemo)radition

Ondersteuning

Primaire sponsor: Internal sponsorship of the LUMC
Overige ondersteuning: LUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To study the correlation between EMG values of the pelvic floor and functional outcomes of patients who has been treated for rectal cancer in the period January 2015 till December 2017.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
The prognosis of rectal cancer has improved in the last decade. As rectal cancer patients often survive their disease, functional outcome after rectal cancer treatment has become increasingly important. Patients without a permanent colostomy can experience significant rates of faecal incontinence and other anorectal complaints such as frequency, urgency and flatulence. Moreover, after rectal cancer treatment urinary incontinence, difficulty in bladder emptying and sexual dysfunction is seen. These functional outcomes have impact on quality of life (QoL).
The rectum, anal sphincters, bladder, urethra and pelvic floor muscles are essential in maintaining faecal and urinary continence. Surgery and radiotherapy for rectal cancer treatment can cause damage to these components which can lead to involuntary loss of faeces and urine. In patients with already existing pelvic floor dysfunction, additional damage to pelvic floor muscles and pelvic nerves is expected to further impair the continence mechanism and is expected to result in worse functional outcomes. In short, we expect pre-treatment function of the pelvic floor to influence post-treatment functional outcomes. However, no diagnostic tool is used to objectively measure the function of the individual muscles of the pelvic floor in patients with rectal cancer. We expect that measurement of the pelvic floor with electromyography (EMG) is correlated to patients' postoperative functional outcomes. If so, measurement of pre-treatment pelvic floor function with EMG may possibly predict the functional outcomes after rectal cancer treatment, and therefore determine treatment choices to a certain extent.
In this study the correlation between post-treatment EMG values of the pelvic floor and post-treatment functional outcomes will be evaluated. When a positive correlation is found, a successive study will be conducted to determine whether pre-treatment EMG measurement of the pelvic floor is predictive for the post-treatment functional outcomes. If so, patients and doctors can be informed about the expected functional outcomes, which can contribute in decision making for the surgeon to construct a permanent stoma instead of sphincter preservation during Low Anterior Resection (LAR) and it can contribute to make decisions about participating in the organ sparing 'wait-and-see' treatment.
Main objective:
To study the correlation between EMG values of the pelvic floor and functional outcomes of patients who has been treated for rectal cancer in the period January 2015 till December 2017.

Secondary objectives:
- 1) To compare EMG values of the pelvic floor after rectal cancer treatment between

different treatment groups (LAR, LAR preceded by Short Course Radiotherapy (SCRT), LAR preceded by chemoradiotherapy (CRT), or CRT alone).
- 2) To compare functional outcome after rectal cancer treatment between different treatment groups (LAR, LAR preceded by Short Course Radiotherapy (SCRT), LAR preceded by chemoradiotherapy (CRT), or CRT alone).
- 3) To determine a correlation between EMG values of the pelvic floor after (chemo)radiotherapy of the rectum and the radiation dose to the different individual muscles of the pelvic floor.
Study design:
Cross-sectional study.
Study population:
All patients > 18 years treated for rectal cancer (LAR, LAR preceded by SCRT, LAR preceded by CRT, or CRT alone) between January 2015 and December 2017.
Main study parameters/endpoints:
The primary endpoint is the mean EMG value of the pelvic floor 1.5 - 4.5 years after rectal cancer treatment. The mean EMG value will be compared to the functional outcomes defined in the Low Anterior Resection Syndrome (LARS) score at 1.5 - 4.5 years after rectal cancer treatment, to study a correlation.
Secondary endpoints are the development of faecal incontinence, LARS symptoms, urinary incontinence, urinary symptoms and sexual dysfunction at 1.5 -4.5 years after rectal cancer treatment.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Patients included in the study will have 1 additional hospital visit that will last 1 hour. During this visit, an EMG measurement of the pelvic floor will be performed. This will be done with a small anal probe, the Multiple Array Probe Leiden (MAPLe®), manufacturer Novuqare BV., CE: 0344.
No risks are associated with the use an anal probe..
After the measurement, patients will receive questionnaires about defecation, micturition and sexual functioning. These questionnaires contain 24 questions for women and 24 questions for men in total. Patients can complete the questionnaire at home.
Patients will have no direct benefit from participation in this study.

Doel van het onderzoek

In this study the correlation between post-treatment EMG values of the pelvic floor and post-treatment functional outcomes will be evaluated. When a positive correlation is found, a successive study will be conducted to determine whether pre-treatment EMG measurement of the pelvic floor is predictive for the post-treatment functional outcomes. If so, patients and doctors can be informed about the expected functional outcomes, which can contribute in decision making for the surgeon to construct a permanent stoma instead of sphincter preservation during Low Anterior Resection (LAR) and it can contribute to make decisions about participating in the organ sparing ‘wait-and-see’ treatment.

Onderzoeksopzet

NA

Onderzoeksproduct en/of interventie

Questionnairres and anal measuremnet with a probe of the EMG signals of the pelvic floor

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

To be eligible to participate in this study, a subject must meet all the following criteria:
- The patient underwent treatment for rectal cancer by LAR, LAR preceded by SCRT, LAR preceded by CRT or CRT alone in the period January 2015 till December 2017.
- > 18 years of age.
- Proficiency of the Dutch language.
- Able and willing to read and fill in questionnaires.
- Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation

in this study:
- Patients who underwent abdomino- perineal resection (APR) or Hartman resection.
- Patients with a diverting colostoma.
- Neurological comorbidity (spinal lesion or cerebrovascular accident (CVA)) or muscle disease (Multiple Sclerosis (MS)).
- Patients who deceased
- Patients with a local relapse
- Patients with metastasis in a distant organ

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-01-2020
Aantal proefpersonen:	46
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:	31-10-2019
Soort:	Eerste indiening

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	NL8127
Ander register	METCLDD : METCLDD P19.085

Resultaten