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

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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 2014 till December 2018.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational invasive

Summary

ID

NL-OMON55378

Source
ToetsingOnline

Brief title
EFFORT trial

Condition

- Muscle disorders

Synonym
Pelvic floor function, rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electromyography (EMG), Functional outcomes, Pelvic floor, Rectal cancer

Outcome measures

Primary outcome

The primary endpoint is the EMG value of the pelvic floor measured in a patient who underwent rectal cancer treatment 1.5 * 4.5 years ago, measured as:

- The mean of 10 x maximum voluntary contraction (MVC), where patients are instructed to perform 10 times a controlled contraction and relaxation of the pelvic floor muscles.

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 outcome

- The functional outcome at 1.5-4.5 years after rectal cancer treatment expressed in Low Anterior Resections Syndrome (LARS) score.
- Faecal incontinence at 1.5 * 4.5 years after rectal cancer treatment defined in the Vaizey score.
- Urinary incontinence at 1.5 -4.5 years after rectal cancer treatment expressed in the International Consultation on Incontinence Questionnaire Urinary Incontinence (ICIQ *UI) score.
- Urinary complaints at 1.5 * 4.5 years after rectal cancer treatment expressed in the International Prostate Symptome Score (IPSS).
- Erectile dysfunction in men at 1.5 -4.5 years after rectal cancer treatment defined in the International Index of Erectile Function (IIEF-5).

- Discomfort or pain during sexual intercourse in women at 1.5 -4.5 years after

rectal cancer treatment defined in the EORTC-IL 34 questionnaire

- Radiation dose to the different individual muscles of the pelvic floor.

Study description

Background summary

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.

Study 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 2014 till December 2018.

Study design

Cross-sectional study.

Study burden and risks

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 an small anal probe, the Multiple Array Probe Leiden (MAPLe).
No risks are associated with the use of the MAPLe.
After the measurement, patients will receive questionnaires about defecation, micturition and sexual functioning. These questionnaires contain 25 questions for women and 28 questions for men in total. Patients are able to complete the questionnaires in a quiet room in the LUMC.
Patients will have no direct benefit from participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male and female patients who were treated for rectal cancer in the LUMC by Low Anterior Resection (LAR), LAR preceded by Short Course RadioTherapy (SCRT <= 5x5 Gy), LAR preceded by ChemoRadioTherapy (CRT<= 25 fractions of 2 Gy with concurrent capecitabine chemotherapy 825 mg/m2 bid), or CRT in a *wait-and-see* trial.
- > 18 years of age.
- Proficiency of the Dutch language.
- Able and willing to fill in questionnaires alone or with help.
- Written informed consent.

Exclusion criteria

- Patients who underwent abdominoperineal resection (APR) or Hartman resection.
- Patients with a diverting colostoma.
- Neurological comorbidity (spinal laesion 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

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2020
Enrollment:	46
Type:	Actual

Medical products/devices used

Generic name:	Multiple Array Probe Leiden (MAPLe);anale probe
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-11-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	12-03-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	23-06-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	03-04-2021

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL66093.058.19