Prospective multicenter observational cohort to assess quality of life, cost-effectivity and functional outcomes following minimal invasive surgical techniques for rectal cancer in ‘dedicated centers’

Gepubliceerd: 15-09-2021 Laatst bijgewerkt: 13-12-2022

QoL, CE and functional outcomes differ significantly between L-TME, R-TME and TaTME.

Ethische beoordeling	Positief advies
Status	Deelnemers gezocht
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20512

Bron
NTR

Verkorte titel
Vantage

Aandoening

Rectal carcinoma

Ondersteuning

Primaire sponsor: University Medical Center Groningen.
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to compare QoL at 1 year postoperatively between L-TME, R-TME, and TaTME.

Toelichting onderzoek

Achtergrond van het onderzoek

Total mesorectal excision is the standard of care for rectal cancer, which can be performed using open, laparoscopic, robot-assisted, and transanal technique. Large prospective (randomized controlled) trials comparing these techniques are lacking, do not take into account the learning curve, and have short term or long-term oncological results as their primary endpoint, without addressing quality of life (QoL), cost-effectiveness (CE) and functional outcomes. Comparative data with regard to these outcomes is necessary to identify the optimal minimal invasive technique and provide guidelines for clinical application.

The Vantage trial will be a prospective observational multicenter cohort trial, aiming to compare laparoscopic (L-TME), robot-assisted (R-TME) and transanal (TaTME) total mesorectal excision in adult rectal cancer patients performed by experienced surgeons in dedicated centers. Data collection will be performed in collaboration with the prospective Dutch ColoRectal Audit and the Prospective Dutch ColoRectal Cancer Cohort. QoL at 1 year postoperatively will be the primary outcome. CE, functional outcomes, short term outcomes, and long-term oncological outcomes will be the secondary outcomes. In total, 1200 patients will be enrolled over a period of two years in twenty-six dedicated centers in the Netherlands.

Data will be collected through collaborating parties, who already obtained approval by their medical ethical committee. Participants will be included in the vantage trial after having signed informed consent. Results of this study will be disseminated to participating centers, patient organizations, (inter)national society meetings, and peer-reviewed journals.

Doel van het onderzoek

QoL, CE and functional outcomes differ significantly between L-TME, R-TME and TaTME.

Onderzoeksopzet

PLCRC will provide the current study with:
QoL outcomes, collected through the EORTC QoL Questionnaire-Core questionnaire (QLQ-C30) and EORTC QoL Questionnaire ColoRectal Cancer module (QLQ-CR29) sent at baseline, three, six, 12, 18 and 24 months postoperative.

CE outcomes, collected through the EQ-5D and WAI at baseline, three, six, 12, 18 and 24 months postoperative. And through the iMCQ at three, six, 12, 18 and 24 months postoperative.

Functional outcomes, collected through Low Anterior Resection Syndrome (LARS) Questionnaire, Macoy Female Sexuality Questionnaire (MFSQ), International Index of Erectile Function (IIEF), Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) sent at baseline, three, six, 12, 18 and 24 months postoperative.

The DCRA will provide the current study with:
Short term outcomes and baseline characteristics, collected at 90 days postoperative, including patient, imaging, perioperative and histopathological characteristics.

Additionally, Vantage will collect data not provided by DCRA and PLCRC: imaging characteristics (sigmoidal take-off, low rectal tumors defined according to the LOREC definition, ycTNM staging) and long term oncological and stoma outcomes (complications, anastomotic leakage (significant for CE and QoL)).

Onderzoeksproduct en/of interventie

Not applicable.

Contactpersonen

Algemeen / deelnemers

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Wetenschappers

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients receiving L-TME, R-TME and TaTME between October 2021 and October 2023 in participating centers will be assessed for eligibility for inclusion. Included will be patients aged ≥ 18 years, registered in the DCRA database, diagnosed with rectal cancer defined as the lower border of the tumor under the sigmoidal take off, undergoing elective and curative treatment in a dedicated center.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

There are no predefined exclusion criteria.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Toewijzing zonder loting
Blindering:	Open / niet geblindeerd
Controle:	Niet van toepassing / onbekend

Deelname

Nederland

Status:	Deelnemers gezocht
(Verwachte) startdatum:	04-10-2021
Aantal proefpersonen:	1200
Type:	Onderzoek is nog niet gestart, dit is de verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	15-09-2021
Soort:	Eerste beoordeling onderzoek

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	NL9734
Ander register	Data will be collected through collaborating parties, who already obtained approval by their medical ethical committee. The PLCRC received approval by the METC Utrecht 17-06-2014. : 12/510

Resultaten