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COLOR III Trial: Transanal vs Laparoscopic TME (COLORIII)

ClinicalTrials.gov Identifier: NCT02736942

Recruitment Status : Enrolling by invitation
First Posted : April 13, 2016
Last Update Posted : May 3, 2016

Sponsor:
VU University Medical Center

Information provided by (Responsible Party):
H.J. Bonjer, VU University Medical Center

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Study Description

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Brief Summary:

Background Surgery for mid and low rectal cancer is associated with relative high rates of incomplete mesorectal excisions and high rates of circumferential resection margin (CRM) involvement resulting in significant number of local recurrences. Moreover, patients with mid and low rectal cancer suffer from high rates of morbidity, permanent colostomies and impairment of quality of life. The transanal TME (TaTME) has been developed to improve the quality TME in mid and low rectal cancer.

Study design The **COLOR III** trial is an international multicentre randomised study comparing short- and long-term outcomes of TaTME and laparoscopic TME for rectal cancer. The study will include a quality assessment phase before randomisation to ensure required competency level and uniformity of the new TaTME technique and the laparoscopic TME. During the trial clinical data will be reviewed centrally to ensure uniform quality.

Endpoints Primary endpoint is involvement of CRM. Secondary endpoints include morbidity and mortality, residual mesorectum (postoperative MRI), local recurrence, disease-free and overall survival, percentage of sphincter saving procedures, functional outcome and quality of life.

Statistics In laparoscopic TME the percentage of involved CRM is estimated 7%. To detect a reduction to 3% with a two-sided level of significance of 5% and a power of 80% a total of 1098 patients is needed. Randomisation will be in a 2:1 ratio in favour of the TaTME procedure. It will be stratified for T-stage, preoperative radiotherapy, height of the tumour, gender and BMI. All analyses will be on intention-to-treat basis.

Main selection criteria Patients with a histologically proved single mid or low rectum carcinoma (0-10cm from anal

verge) on MRI, eligible for TME surgery with a curative intent, are included. Main exclusion criteria are T4 tumours, T3 tumours with a suspected involved mesorectal fascia (MRF) after neoadjuvant therapy, patients with concomitant metastases or other malignancies, with malignancies in their medical history or with signs of acute mechanical obstruction by the tumour.

Hypothesis The hypothesis is that TaTME will result in a better mesorectum specimen quality with a lower rate of involved CRM and therefore lower rate of local recurrence. Furthermore, the TaTME procedure will potentially enable more sphincter saving procedures and will have positive effect on functional outcome and health related quality of life.

Condition or disease	Intervention/treatment	Phase
Rectal Carcinoma Surgery	Procedure: Laparoscopic TME Procedure: TaTME	Phase 3

Detailed Description:

To improve oncological and functional outcomes of patients with rectal cancer new surgical techniques are being developed. The adoption of the TME technique has resulted in better oncological outcome in the last decades. The addition of neoadjuvant therapy has further improved oncological outcome. The minimal invasive laparoscopic resection of rectal cancer has shown to be safe and to result in improved short-term outcomes and reduced morbidity.

Nevertheless, the laparoscopic resection of mid and low rectal cancer remains challenging due to the anatomy of the narrow pelvis and is associated with a relative high risk of resections with tumour involved CRM resulting in increased risk of recurrence.

In attempt to improve the quality of the TME procedure in low rectal cancer and further improve oncological results the TaTME has been developed, in which the rectum is dissected transanally according to TME principles. First series have been described since 2010 and although randomised evidence is still lacking this new technique has shown to be feasible and safe. The rectum including the total mesorectum is mobilised transanally in a reversed way with minimally invasive surgery including high quality imaging techniques.

The TaTME technique for mid and low rectal cancer has shown to have potential benefits: better specimen quality with less CRM involvement, less morbidity as result of avoiding extraction wounds in the majority of patients and more sphincter saving rectal resections without compromising oncological outcomes.

The investigators propose to evaluate the TaTME technique compared with conventional laparoscopic rectal resection for patients with mid and low rectal cancer in an international randomised trial: the COLOR III trial.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	1098 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	**COLOR III**: A Multicentre Randomised Clinical Trial Comparing Transanal TME Versus Laparoscopic TME for Mid and Low Rectal Cancer
Study Start Date :	May 2016
Estimated Primary Completion Date :	May 2020
Estimated Study Completion Date :	May 2025

Arms and Interventions

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Arm	Intervention/treatment
Active Comparator: Laparoscopic Laparoscopic TME	Procedure: Laparoscopic TME Laparoscopic Total Mesorectal Excision
Experimental: Transanal TaTME	Procedure: TaTME Transanal Total Mesorectal Excision

Outcome Measures

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Primary Outcome Measures :

1. Percentage of participants with involvement of circumferential resection margin (tumour cells < 1mm from circumferential resection margin) [Time Frame: 4 years]

   Pathological microscopic examination of specimen

Secondary Outcome Measures :

1. Morbidity rate [Time Frame: 5 years]
2. Mortality rate [Time Frame: 5 years]
3. Percentage of participants with recurrence [Time Frame: 5 years]

   Local and distant.

4. Disease-free survival rate [Time Frame: 5 years]
5. Overall survival rate [Time Frame: 5 years]
6. Percentage of sphincter saving procedures [Time Frame: 4 years]
7. Change in functional outcomes (LARS questionnaire) [Time Frame: Baseline and 1 year]

   Measured by questionnaires

8. Change in Health Related Quality of Life (EORTC QLQ-29 questionnaire) [Time Frame: Baseline and 1 year]

   Measured by questionnaires

9. Change in Health Related Quality of Life (EORTC QLQ-30 questionnaire) [Time Frame: Baseline and 1 year]

   Measured by questionnaires

10. Change in Health Related Quality of Life (EQ 5-D questionnaire) [Time Frame: Baseline and 1 year]

    Measured by questionnaires

Eligibility Criteria

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Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Senior)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Solitary mid (5.1-10cm from anal verge on MRI) or low (0-5cm from anal verge on MRI) rectal cancer observed at colonoscopy and histologically proven through biopsy
- Distal border of the tumour within 10cm from the anal verge on MRI-scan
- Tumour with threatened margins downstaged after neoadjuvant therapy to free margins
- No evidence for distal metastases on imaging of thorax and abdomen
- Suitable for elective surgical resection
- Informed consent according to local requirements

Exclusion Criteria:

- T3 tumours with margins less than 1mm to the MRF, determined by MRI-scan (as staged after preoperative chemo- and/or radiotherapy)
- T4 tumours, as staged after preoperative chemo- and/or radiotherapy
- Tumours with in growth more than 1/3 of anal sphincter complex or levator ani
- Malignancy other than adenocarcinoma at histological examination
- Patients under 18 years of age
- Pregnancy
- Previous rectal surgery (excluding local excision, EMR (endoscopic mucosal resection) or polypectomy)
- Signs of acute intestinal obstruction
- Multiple colorectal tumours
- Familial Adenomatosis Polyposis Coli (FAP), Hereditary Non-Polyposis Colorectal Cancer (HNPCC), active Crohn's disease or active ulcerative colitis
- Planned synchronous abdominal organ resections
- Preoperative suspicion of invasion of adjacent organs through MRI-scan
- Preoperative evidence for distant metastases through imaging of the thorax and abdomen
- Other malignancies in medical history, except adequately treated basocellular carcinoma of the skin or in situ carcinoma of the cervix uteri
- Absolute contraindications to general anaesthesia or prolonged pneumoperitoneum, as severe cardiovascular or respiratory disease (ASA class > III)

Contacts and Locations

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To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02736942***

Locations

Netherlands

VU University Medical Center
Amsterdam, Netherlands

Sponsors and Collaborators

VU University Medical Center

Investigators

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Responsible Party:	H.J. Bonjer, Professor of Surgery, MD, PhD, FRCSC, VU University Medical Center
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Other Study ID Numbers:	2015.449
First Posted:	April 13, 2016 Key Record Dates
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Last Verified:	May 2016

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD:	No
Plan Description:	We are not sharing confidential individual patient data.