



COLOR III study - A Multicenter Randomized Clinical Trial Comparing Transanal versus Laparoscopic Total Mesorectal Excision for Mid and Low Rectal Cancer

Patients with (y)cT1-3N0-2M0 low or mid rectal cancer¹

Informed Consent + Registration + uploading MRI files / report²

Eligibility³

Randomization⁴

TaTME⁵ 2 : 1 Lap TME⁵

Primary Outcome⁶
Local recurrence at 3-years
(non-inferiority design)

Secondary Outcomes⁷
Pathology, HrQOL, DFS, OS, etc.

CENTRAL
REVIEW

MRI

VIDEO

MRI / CT

PATHOLOGY

CONTACT INFORMATION

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INCLUSION

1. Adenocarcinoma
2. T1-3 MRF > 1 mm N1-2 M0
3. 0 - 10cm from ab ano on MRI
4. TME with anastomosis
5. Elective surgery

EXCLUSION

1. MRF ≤ 1 mm
2. T4 rectal cancer
3. Distant metastasis
4. TME without anastomosis
5. Emergency surgery

Months	1	3	6	9	12	18	24	36	48	60
Clinical Evaluation		X	X	X	X	X	X	X	X	X
CEA		X	X	X	X	X	X	X	X	X
Colonoscopy					X				X	
CT-thorax / abdomen or CXR and ultrasound liver			X		X	X	X	X	X	X
MRI / CT - Pelvis								X		
<i>HrQoL and function*</i>	X	X	X		X		X	X		

1. All inclusion and exclusion criteria written in protocol.
2. Enter TENALEA <https://prod.tenalea.net/colorIII/DM/> to complete registration form.
3. Upload the MRI (DICOM files), report and MRI form in TENALEA.
4. After approval radiologist, the patient will be randomized in TENALEA.
* Please send email of patient and planned surgery date to colortrial@vumc.nl.
5. Upload the surgical procedure, abdominal phase and if applicable transanal phase.
Always include the extraction of the specimen and construction of the anastomosis.
6. Upload MRI / CT scan of pelvis at 3-years or when recurrence is diagnosed.
7. Upload Pathology images according to the guideline in the protocol.

More information?

www.color3trial.com