A randomised Phase III feasibility study to compare radical TME surgery versus preoperative (chemo)radiotherapy and watchful waiting or local excision for treatment of early stage rectal cancer.

Published: 16-12-2019
Last updated: 10-04-2024

nvt

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON55049

Source
ToetsingOnline

Brief title
STAR-TREC

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: University of Birmingham

Source(s) of monetary or material Support: KWF

Intervention

Keyword: Chemotherapy, Radiotherapy, Rectal cancer, Surgery

Outcome measures

Primary outcome

nvt

Secondary outcome

nvt

Study description

Background summary

nvt

Study objective

nvt

Study design

nvt

Intervention

nvt

Study burden and risks

nvt

Contacts

Public

University of Birmingham

Research Support Group, Aston Webb Building 119
Birmingham B152TT
GB
Scientific
University of Birmingham

Research Support Group, Aston Webb Building 119
Birmingham B152TT
GB

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Biopsy proven adenocarcinoma of the rectum
• MRI <=T3b N0 M0 rectal tumour
• MDT determines that the following treatment options are all reasonable and feasible: (a) TME surgery, (b) CRT, (c) SCRT and (d) TEM
• ECOG status 0-1

Exclusion criteria

• MRI node positive (defined by protocol guidelines)
• MRI extramural vascular invasion (mriEMVI) present (defined by protocol guidelines)
• MRI defined mucinous tumour
• Mesorectal fascia threatened by tumour (<= 1mm on MRI)
• Maximum tumour diameter > 40mm; measured from everted edges on sagittal MRI
• Anterior tumour location above the peritoneal reflection on MRI or ERUS

• No residual luminal tumour following endoscopic mucosal resection • Prior pelvic radiotherapy
• Regional or distant metastases • Age <16 years (UK), <18 years (Netherlands/ Denmark)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-10-2020
Enrollment:	150
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Capecitabine
Generic name:	Capecitabine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	16-12-2019

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-05-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-08-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-01-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-03-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-06-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-08-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-01-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-02-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-04-2023

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2019-004669-41-NL
CCMO	NL72230.091.19