Can we Save the rectum by watchful waiting or TransAnal microsurgery following (chemo)Radiotherapy versus Total mesorectal excision for early Rectal Cancer? - STAR-TREC study

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This study has been transitioned to CTIS with ID 2024-516106-31-00 check the CTIS register for the current data. STAR-TREC is a phase II feasibility study that will evaluate whether it is possible to accelerate patient recruitment from 2 per month,...

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

Summary

ID

NL-OMON47279

Source
ToetsingOnline

Brief title
STAR-TREC

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
rectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Chemotherapy, Radiotherapy, Rectal cancer, Surgery

Outcome measures

Primary outcome

1. Year 1: randomise at least 4 cases per month internationally (n=48);

2. Year 2: randomise at least 6 cases per month internationally (n=72).

Secondary outcome

1. Can one international partner procure independent funding in year 1?

2. Can one international partner open the study to recruitment in year 1?

3. Organ saving rate in the experimental arms at 12 months (from randomisation)

4. Proportion of patients undergoing TME surgery accurately staged and

satisfying inclusion/ exclusion criteria

5. Proportion of patients identified by MRI suitable for active monitoring

based on mrTRG assessment

6. 3 year pelvic failure rate defined as the proportion of patients in each arm

with:

a. unresectable pelvic tumor

b. pelvic tumour requiring beyond TME surgery

c. <=1mm circumferential resection margin after TME surgery

7. Overall survival

8. Stoma free survival

9. Health Related Quality of Life (HR QoL)

Study description

Background summary

More than 3500 patients are annualy diagnosed with rectal cancer in the Netherlands. The introduction in 2014 of our national bowel screening program will further increase the number of patients. This increase will lead to a high number of patients with early stage rectal cancer (T1-3N0M0). Prognosis of these patients is generally good with more than 80% surviving 5 years after surgery. A partial or total mesorectal excision will be performed and a (temporary) colostomy is frequently performed. Moreover, patients often experience defaecation, urinary and sexual disorders. Recent studies demonstrated that selected patients could be treated with local excision after chemoradiation treatment leading to organ preservation. Several studies have been performed including the CARTS study, and demonstrated organ preservation in up to 70% of
patients after chemoradiation therapy. This treatment was not always tollerated well and severe complications have been described. In the UK a similar organ preservation protocol has been developed using radiotherapy only. This treatment seemed to have less complications, but results on organ preservation are to be awaited. Since these studies have been performed recently, it is unknown if the excellent long term results after standard surgery are equipoised by these organ preservation techniques. It is therefore important to study which technique the optimal results are reached: 1) chemoradiation followed by organpreservation, 2) radiation therapy followed by organ preservation or 3) standard surgery. The best way studying this is by a randomised trial. Because these treatment modalities differ significantly we aim to study in an (international) trial if randomisation is feasible. If this succeeds a concurrent phase III trial will be started, studying the optimal treatment for patients with early rectal cancer.

Study objective

This study has been transitioned to CTIS with ID 2024-516106-31-00 check the CTIS register for the current data.

STAR-TREC is a phase II feasibility study that will evaluate whether it is possible to accelerate patient recruitment from 2 per month, as attained in the previous TREC study, to 6 per month over a two-year period. This would demonstrate deliverability of a phase III study incorporating 400 patients to evaluate differences in pelvic relapse rates between organ saving and standard surgery (see sample size calculation). Randomising 70-80 patients per year in

phase III would achieve this target in 4 years (including patients treated in phase II).

Study design

Randomised fase II feasibility study

Intervention

Three arm (1:1:1) randomisation using the following arms:
1. Standard TME surgery (control)
2. Organ saving using:
a. long course concurrent chemoradiation
b. short course radiotherapy
For organ-preserving strategies clinical response to radiotherapy determines the next treatment step. Radiotherapy response is evaluated using endoscopy and mriTRG. The first assessment at 11-13 weeks (from radiotherapy start) using MRI and endoscopy will identify a minority of non-responders who should convert to TME surgery. Patients demonstrating a satisfactory radiotherapy response at 11-13 weeks will be reassessed by endoscopy at 16-20 weeks. Re-evaluation determines if the STAR-TREC criteria for complete clinical response (cCR) are met. Patients who achieve cCR may progress directly to active surveillance. Those who do not fulfil the criteria for cCR will progress to excision biopsy with TME.

Study burden and risks

What are the benefits of standard treatment?
Standard treatment with radical surgery to remove the rectum has been used successfully to treat both small and large rectal cancers for many years and we know that it usually cures rectal cancer. We think that only 3 - 6 in out of every 100 patients with small rectal cancers treated by radical surgery will have their cancer come back in the pelvis. A larger number, perhaps 10-15 in every 100 will have the cancer return in the liver or lungs. This means that around 9585% of patients treated in this way are likely to be cured of cancer.

What are the risks of standard treatment?
Like any major operation, radical surgery may result in serious side effects. The risk of death due to radical surgery to remove the rectum is roughly 4 in every 100 operations. The level of risk depends upon age and overall physical fitness. For example, in patients aged 75 - 85 years the risk of death can be as high as 15 out of every 100 cases.
One of the most serious complications after standard radical surgery is a leak of faeces from the bowel where it has been joined to the anus. If this problem arises, then more surgery is usually required to control the situation. This often involves rerouting the bowel through the tummy wall into a bag (stoma).

Although we always do our best to avoid leaks they remain quite common. Leaks complicate 5 to 15 out of every 100 operations. Your surgeon will be able to tell you about complication rates in your own local hospital. As mentioned earlier your surgeon can reduce this risk by creating a temporary, diverting stoma bag for you at they time of your rectal cancer operation.

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

• Biopsy proven adenocarcinoma of the rectum
• MRI T1-3b N0 M0 rectal tumour
• MDT determines that the following treatment options are all reasonable and feasible: (a) TME surgery, (b) CRT, (c) SCPRT and (d) TEM

• Estimated creatinine clearance >50 ml/min

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:	2
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):	04-07-2017
Enrollment:	75
Type:	Actual

Medical products/devices used

Product type:	Medicine

Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-05-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-03-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-08-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-02-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-08-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-11-2019
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
EU-CTR	CTIS2024-516106-31-00
EudraCT	EUCTR2016-000862-49-NL
CCMO	NL53181.091.16