CHEMORADIOTHERAPY FOR RECTAL CANCER IN THE DISTAL RECTUM FOLLOWED BY ORGAN-SPARING TRANSANAL ENDOSCOPIC MICROSURGERY
CARTS study
CApecitabine, Radiotherapy and Tem Surgery. A PHASE II, FEASIBILITY TRIAL

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

Summary

ID

NL-OMON35364

Source
ToetsingOnline

Brief title
TEM after radiochemotherapy for rectal cancer

Condition

- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
rectal cancer. Distal colon cancer

Research involving
Human

Sponsors and support

Primary sponsor: Dutch Colorectal Cancer Group
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Organpreservation, Radiochemotherapy, Rectal Cancer, TEM

Outcome measures

Primary outcome

Primary endpoint is the response of the rectal carcinoma to chemo-/radiotherapy defined as complete response (no visible disease); partial response (more than 50% reduction of the tumour mass); no response (meaning an increase of the tumour mass less than 25% or a decrease of the tumour mass less than 50%); or progressive disease when the tumour mass increase more than 25% of the original tumour mass.

Secondary outcome

Quality of life. Occurrence of local recurrence. Toxicity. Number of positive lymphnodes in patients who have been treated with classical surgery. The number of sphincter saving procedures after organ sparing surgery by TEM or after classical TME surgery.

Study description

Background summary

In the Netherlands approximately 2300 new patients are diagnosed with rectal cancer each year. Standard treatment for patients with a T2 or T3 rectal cancer consists of preoperative short course of radiotherapy followed by surgery. In advanced cases long course of radiotherapy combined with chemotherapy is used instead of a short cause. In some of these advanced cases a complete remission is observed after a long course of radio-/chemotherapy. Patients who respond well to neo-adjuvant treatment carry a better prognosis.

Study objective

Objective of this research is to evaluate whether neo-adjuvant chemo-/radiotherapy in small non-advanced rectal cancers can be used to obtain a complete or near complete remission. In these patients could a complete resection of the rectum as an organ be avoided by treating them with a local excision with the TEM-technique (Transanal Endoscopic Microsurgery) of the scar. The advantage for these patients is, that they do not need major abdominal surgery and in a substantial number of these patients the rectum can be preserved with a better function of continence.

Study design

Patients ,hich from a technical point of view, could be treated by a TEM resection are candidate for this study. Regardless of their primary T-stage: T-stage 1, 2 and 3 may participate. However, T-stage should be evaluated with both endo-sonographic and MRI imaging techniques. Patients will receive radio-/chemotherapy for a period of 6 weeks. After a waiting period of 6 weeks a complete re-staging takes place again consisting of endo-sonography and MRI. Patients who did not respond well to the neo-adjuvant treatment and still have a T3 tumour will be treated in a classical way by standard total mesorectal excision (TME) surgery. All patients in whom the tumour did regress to stage T0 or stage T1 or T2 will be operated by a TEM technique. The reason to include T2 stage patients is that both by endo-sonography or MRI after radio-/chemotherapy a tendancy for overstaging exist. That is reason to include them for TEM. If, on final pathology, is seen, that the tumour was completely regressed to T0 or nearly completely regressed to stage T1 without lymfangio invasion, no further surgical treatment will take place. All patients who still have a T2 tumour or more will have to undergo salvage TME surgery.

Intervention

The intervention consists of the use of radio-/chemotherapy for 6 weeks followed by complete re-staging and a TEM procedure if the patient is suitable after re-staging.

Study burden and risks

The majority of these patients will be treated with local excision of the scar of their primary tumor by a TEM procedure in stead of a major abdominal procedure. Chance of postoperative morbidity and mortality is considerably reduced. Furthermore, these patient will not require a temporary or permanent stoma. Only those patients that did not respond well enough to the radiochemotherapy will have standard TME surgery. These patients, if not identified after secondary staging, will have undergone a TEM procedure and still will have to undergo a standard TME procedure as well. For these patients the definitive procedure will be the same as the one that they would have undergone if they had not participated in the study

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

•Patients (aged >18 years) with histological proven adenocarcinoma of the distal third of the rectum without signs of distant metastases.
•T1-3 tumor without lymph nodes > 5 mm at CT, MRI and endoanal ultrasound.
•ANC > 1.5 x 10g/l.
•Thrombocytes > 100 x 109/l.
•Creatinin clearance >50ml/min (according to the Cockcroft-Gault formule)
•Total serum bilirubin < 24 mmol/l or below <1.5 times the upper limit of the normal.
•ASAT,ALAT: up to 5 times the upper limit.
•Colonoscopy, colonography or virtual colonoscopy should exclude synchronous colorectal lesions in other parts of the colon.
•ECOG performance score 0-2.
•Fertile women should have adequate birthcontrol during treatment.
•Mental/physical/geographical ability to undergo treatment and follow-up.
•Written informed consent (Dutch language).

Exclusion criteria

•Patients with Grade 1-2 T1 tumors (can be treated with TEM surgery without chemoradiation therapy)
•Patients with circular rectal tumor or tumors who are by other means unacceptable for TEM surgery (e.g. intra-analtumors).
•Patients with faecal incontinence prior to the diagnosis of rectal cancer (complaints of soiling due to the tumor will not be an exclusion criterium).
•Severe uncontrollable medical or neurological disease.
•Patients with secondary prognosis determining malignancies.
•Patients who have been treated with radiotherapy on the pelvis.
•Use of Warfarin.
•Uncontrolled active infection, compromised immune status, psychosis, or CNS disease.
•Pregnant or lactating women.
•Clinically significant (i.e. active) cardiovascular disease for example cerebrovascular accidents (<= 6 months prior to randomisation), myocardial infarction (<= 6 months prior to randomisation), unstable angina, New York Heart Association (NYHA) grade II or greater congestive heart failure, serious cardiac arrhythmia requiring medication.
• Evidence of other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates use of Capecitabine or patients at high risk for treatment complications.
History or evidence upon physical examination of CNS disease unless adequately treated (e.g., seizure not controlled with standard medical therapy).

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-11-2010
Enrollment:	55
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	23-04-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-10-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-02-2011

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-03-2011
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-06-2011
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	21-07-2011
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-09-2011
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-04-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-06-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-08-2012
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	EUCTR2010-019233-97-NL
CCMO	NL28982.091.10