Follow up and functional outcome of organ saving treatment in patients with good response to neo-adjuvant (chemo)radiation

Published: 12-08-2014
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The primary objective is to describe the functional outcome of patients that choose for organ saving treatment.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON44162

Source
ToetsingOnline

Brief title
Functional outcome W&S

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
colorectal cancer, rectal neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: functional outcome, organ saving treatment, quality of life, rectal cancer

Outcome measures

Primary outcome

Functional outcome scores of patients that are treated with an organ saving strategy compared to patients who undergo the standard resection as described in literature. Functional outcome will be evaluated with questionnaires (quality of life).

Secondary outcome

* Cumulative risk of local failure within 5 years

* Cumulative risks of disease-free, distant-metastasis free and overall survival within 5 years

* The percentage of patients that choose the alternative strategies instead of traditional strategies and the motivation for their choice

* The compliance to the intensive follow-up schedule

* Early detection of local failure (standard surgery still possible)

Study description

Background summary

Rectal cancer is a common form of cancer. Standard treatment for locally advanced rectal cancer is a long course of neoadjuvant radiation combined with chemotherapy (CRT) followed by resection. However, neoadjuvant CRT induces

downsizing and downstaging, resulting in a complete response in 15-20% of the patients. In these patients surgery may be omitted. In our previous study we obtained good results with an organ saving treatment.
The high proportion of complete and good responders with modern chemoradiation and the improvement in MR-imaging techniques have stimulated a renewed interest in organ saving treatment, with a crucial question whether or not the benefits outweigh the risks. More information is required on both the oncological risk of local failure and the need for salvage surgery and the functional outcome after this treatment. Although the mortality and morbidity associated with radical surgery is avoided (e.g. anastomotic leakage, re-laparotomy, wound and pelvic infection, chronic wound healing disturbances, abscess, colostomy, faecal or urinary incontinence, and sexual dysfunction), the irradiated rectum remains in situ, possibly causing functional problems.

Study objective

The primary objective is to describe the functional outcome of patients that choose for organ saving treatment.

Study design

The proposed study is a prospective observational registration study with *invasive diagnostic procedures*. Patients with a clinical very good response to chemoradiation for rectal cancer are offered organ saving treatment as an alternative to standard TME surgery as a part of our standard patient care. The oncological and functional outcome will be assessed by diagnostic procedures and follow up data as a part of standard patient care, and by additional quality of life questionnaires at four timepoints (figure 1).

Study burden and risks

Questionnaires take approximately 20-30 minutes to complete.

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

*1. > 18 years old
2. Patients with primary rectal cancer without distant metastases who underwent CRT and show clinical complete response or very good response :
2A. Clinical complete response (ycT0N0) after neo-adjuvant chemoradiation will be determined clinically (digital rectal examination, endoscopy) and radiologically (contrast-enhanced-MRI)
2B. Very good response (ycT1-2N0) after neo-adjuvant chemoradiation will be determined clinically (digital rectal examination, endoscopy) and radiologically (contrast-enhanced-MRI). These patients will undergo a TEM to resect the small residual tumor
3. Comprehension of the alternative strategies and the concept of unknown risks are clear to the patient
4. Choosing for the organ-saving treatment option (wait&see policy or TEM)
5. Informed consent

Exclusion criteria

1. Unable to understand or read Dutch
2. Unwilling to comply to the questionnaires or manometric measurement.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-11-2014
Enrollment:	250
Type:	Actual

Ethics review

Approved WMO

Date:	12-08-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	23-11-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL49171.068.14