

# Multicentre evaluation of the \*wait-and-see\* policy for good responders after neoadjuvant (chemo)radiation for rectal cancer

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Malignant and unspecified neoplasms gastrointestinal NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON55431

### Source

ToetsingOnline

### Brief title

Multicentre evaluation of "Wait-and-See" policy for rectal cancer

### Condition

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

### Synonym

colorectal cancer, Rectal cancer

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Antoni van Leeuwenhoek Ziekenhuis

**Source(s) of monetary or material Support:** KWF

## Intervention

**Keyword:** Organ-saving treatment, Rectal cancer, Wait-and-See, Watch-and-Wait

## Outcome measures

### Primary outcome

2-year non-regrowth disease-free survival, defined as absence of non-regrowth local or distant recurrence or death within 2 years of FU.

### Secondary outcome

Secondary study endpoints are:

1. Number of fully operational centres who can deliver high quality organ preserving care in rectal cancer in the Netherlands.
2. 2-year local regrowth rate, defined as the proportion of local regrowth within 2 years of FU.
3. 2-year local control, defined as absence of local recurrence(unresectable regrowth, resected with R1, or requiring more extensive than TME surgery) or death within 2 years of FU.
4. 2-year overall survival, defined as absence of death within 2 years of FU
5. Determination of the optimal follow-up schedule with regard to a balance between early detection of recurrence and compliance to follow-up
6. National registry of all patients treated according to \*wait-and-see\* policy in the Netherlands.
7. Quality of life

# Study description

## Background summary

Standard treatment for patients with locally advanced rectal cancer consists of a long course of chemoradiation (CRT) followed by surgical resection. Although the aim of neoadjuvant treatment in these patients is not organ preservation, but rather to provide improved local control, in 15-20% the tumour disappears completely. Studies from Maastricht, USA and Brazil have shown that in selected patients with a clinical complete response after CRT, a \*wait-and-see\* policy without any surgery could be a safe alternative with comparable long-term outcome and better functional outcome compared to patients who had surgery.

## Study objective

The main objective of the study is to provide short and long term oncological and functional outcome data on organ preserving treatment in good responders after a standard indication for neoadjuvant (chemo)radiation. Additional aims are [1] to set up a national network with expertise centres in the \*wait-and-see\* treatment of rectal cancer [2] to set up a national registry for organ preservation treatment that will generate more evidence on the management and oncological outcome of patients evaluated and treated with organ preservation and [3] to offer through this network to all patients who are considered good candidates this \*wait-and-see\* approach using the most up to date tools for selection and follow-up.

## Study design

Multicentre prospective observational cohort study

## Study burden and risks

The standard treatment (major surgery) after chemoradiation for rectal cancer is associated with perioperative morbidity and mortality, and with long term functional morbidity like urinary and fecal incontinence, sexual dysfunction and a permanent colostomy. In the majority of patients who participate in the study, major surgery and the associated morbidity can be avoided. Although scientific proof shows "wait-and-see" only comes with a small risk, with adequate selection and follow up, the exact risk is not yet well established. If the small oncological risk is confirmed by this study, we may be able to proceed to implement the "wait-and-see" policy as a treatment option in daily clinical practice, leading to a higher quality of life for a substantial number of patients with rectal cancer, without compromising oncological outcome. Therefore, the benefit-risk ratio for this study is

regarded as favourable

## 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 who underwent CRT and show clinical complete response: Clinical complete response (ycT0N0) after neo-adjuvant chemoradiation will be determined clinically (digital rectal examination, endoscopy) and radiologically (MRI)
3. Patients with a clinical good response with a small residual tumour (ycT1-2N0) who decline the recommended TME surgery
4. Comprehension of the alternative strategies and the concept of unknown risks are clear to the patient

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5. Choosing for the "Wait-and-See" policy
6. Informed consent

## Exclusion criteria

1. Recurrent rectal cancer
2. Unable or unwilling to comply to the intensive follow-up schedule.

## Study design

### Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	10-05-2017
Enrollment:	220
Type:	Actual

### Medical products/devices used

Registration:	No
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## Ethics review

Approved WMO	
Date:	10-02-2017
Application type:	First submission
Review commission:	METC NedMec

Approved WMO	
Date:	30-05-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	09-08-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	09-11-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	14-12-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	01-03-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	28-06-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	15-05-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	10-09-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	02-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	

Date:	25-08-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	31-01-2025
Application type:	Amendment
Review commission:	METC NedMec

## 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	NL58095.031.16