

Multicentre evaluation of the “wait-and-see” policy for complete responders after chemoradiotherapy for rectal cancer



Netherlands Cancer Institute
Amsterdam, The Netherlands



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- **Aim:**

“To provide short term and long term oncological and functional outcome data on organ preserving treatment in complete responders after a standard indication for neoadjuvant (chemo)radiation in a multicenter setting”

- **Design:** Multicenter prospective observational cohort study

- **Patients:**

- ≥18 years or older
- Primary rectal cancer (pathologically confirmed)
- Treated with neoadjuvant (chemo)radiotherapy
- cCR to neoadjuvant treatment, determined clinically (DRE, endoscopy) and radiologically ((DWI)-MRI)
- Dutch language

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- (overview study/treatment arms)*

Procedure		Distant metastasis#	CEA	Digital Rectal Exam	Endoscopy /biopsy	MRI	Questionnaires
Year 1	3 mo		x	x	x	x	x
	6 mo	x	x	x	x	x	
	9 mo		x	x	colonoscopy‡		
	12 mo	x	x	x	x	x	x
Year 2	3 mo		x				
	6 mo		x	x	x	x	
	9 mo		x				
	12 mo	x	x	x	x	x	x
Year 3	3 mo						
	6 mo		x	x	x	x	
	9 mo						
	12 mo	x	x	x	x	x	
Year 4	3 mo						
	6 mo		x	x	x	x	
	9 mo						
	12 mo	x	x	x	x	x	
Year 5	3 mo						
	6 mo		x	x	x	x	
	9 mo						
	12 mo	x	x	x	x	x	x

Questionnaires:

- EORTC Q LQ-30 questionnaire, version 3.0
- Short Form 36 health survey
- EORTC CR29
- Vaizey score
- Low Anterior Resection Syndrome (LARS) score
- International Prostate Symptom Score (I-PSS)
- International Index of Erectile Function (IIEF)
- Female Sexual Function Index (FSFI)

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- **Primary endpoint:**

- 2 year non-regrowth disease-free survival

(absence of non-regrowth local or distant recurrence or death within 2 years of FU)

- **Secondary endpoints:**

- Number of fully operational centres

- 2 year local regrowth rate

- 2 year local control

(absence of unresectable regrowth, R1 resection, or regrowth requiring more extensive than TME surgery)

- 2 year overall survival

- Quality of life

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- *Participating centers:*

Antoni van Leeuwenhoek – Netherlands Cancer Institute, Amsterdam

Radboud University Medical Centre, Nijmegen

Isala Clinics, Zwolle

Elisabeth-Tweesteden hospital, Tilburg

Deventer Hospital, Deventer

Maastricht University Medical Centre, Maastricht

Leiden University Medical Centre, Leiden

IJsselland Hospital, Capelle a/d IJssel

VU medical centre, Amsterdam

Westfriesgasthuis, Hoorn

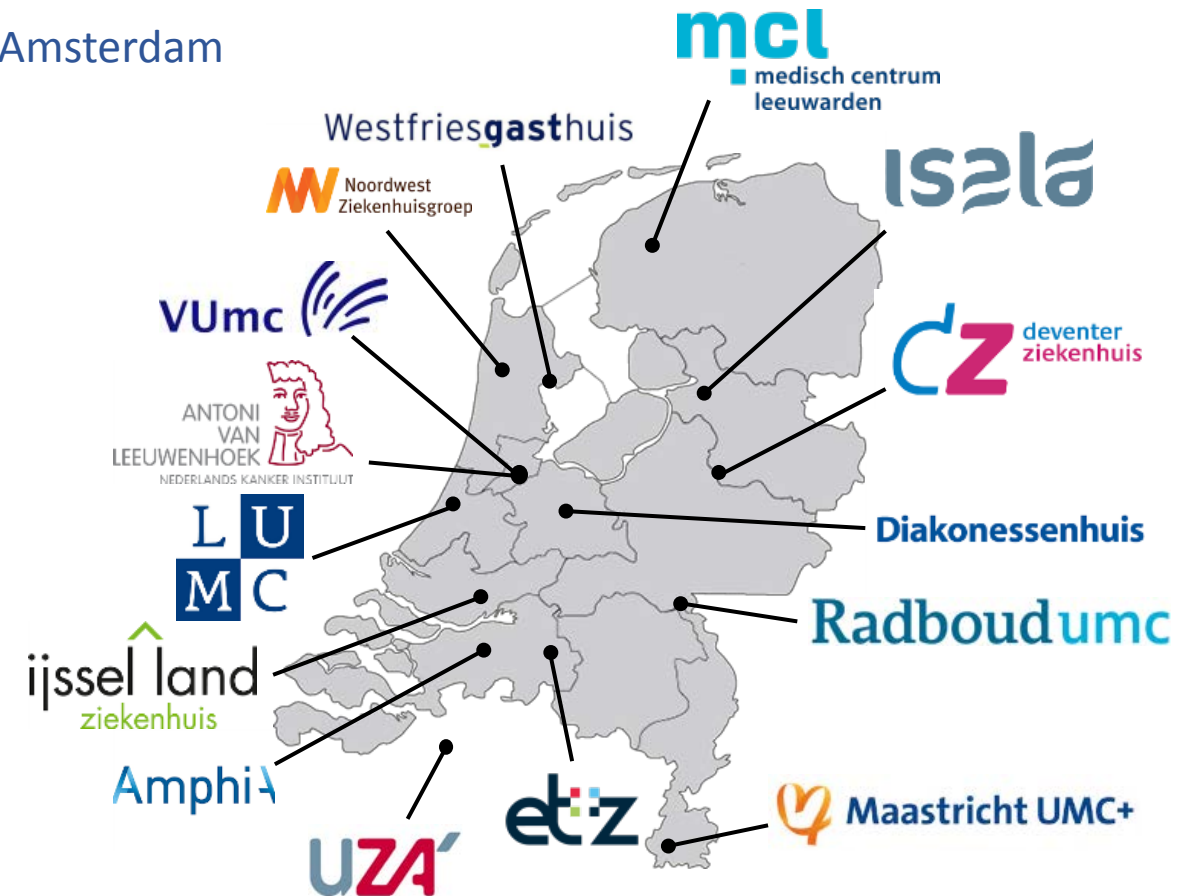
University Hospital Antwerp, Antwerp

Diakonessenhuis, Utrecht

University Medical Centre, Utrecht

Amphia Hospital, Breda

Medical Centre Leeuwarden, Leeuwarden



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- **Number pts needed:** 220 patients
- **Number pts included:** 44 patients (first inclusion May 2017)

- **Contact information:**

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