

# Organ preservation in patients with rectal cancer: A population-based study

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# Background: Clinical complete response rate is uncertain in population-based settings

- **12% (31/259)** Renehan, Lancet Oncol, 2016, 17, 174
- **5% (6/118)** Nahas, Dis Colon Rectum, 2016, 59, 255
- **3%(10/362)** Creavin, Br J Cancer 2017, 16, 169

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# Background cont. Prospective study on predicting cCR, N=201

Gerard, Radiother Oncol 2015;115:246

	cCR	p-value
cT-category		
cT2	28%	0.025
cT3	6%	
cT4	0%	
Tumour diameter		0.017
≤ 4 cm	14%	
> 4 cm	3%	
Mobility		0.08
mobile	10%	
tethered	2%	
<b>fixed n=30</b>	<b>0</b>	

Is organ preservation possible at all for large fixed cT4b lesions?

# Design

Prospective observational population-based study supervised by one experienced institution.

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# Aims

Primary aims;

1. Implementing a watch-and-wait procedure in a population setting: ~8 large radiotherapy departments.
2. Determining the cCR rate in 2 subgroups:
  - with intermediate risk cancer
  - with advanced cancer (mrf+ or cT4b)

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# Aims

Secondary aims are to determining :

1. cCR incidence rate in relation to the tumour characteristics.
2. oncological outcomes
3. anorectal function

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# Entry criteria

1. Consecutive patients undergoing preoperative RT  
and
2. Tumour felt by digital rectal examination

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# Preoperative RT

intermediate risk cancers:

5x5 Gy and **delayed surgery!**

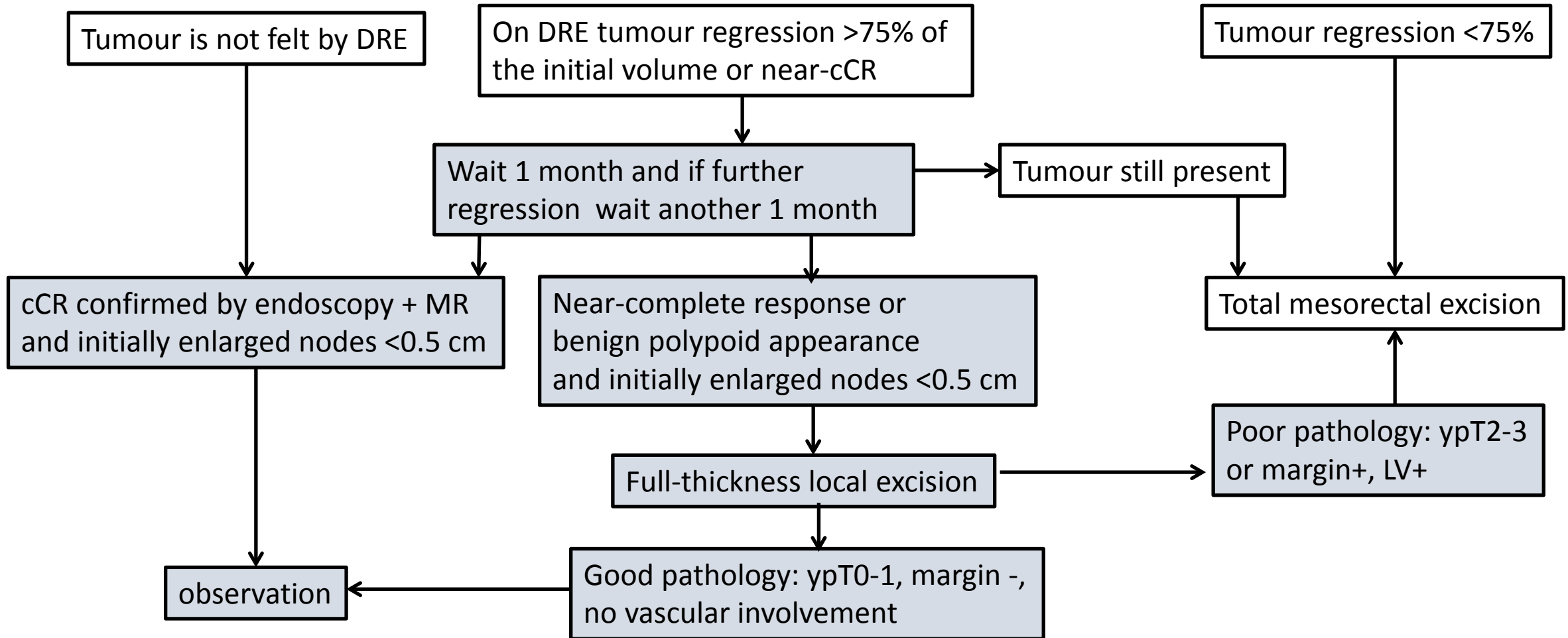
advanced cancers:

1. Chemoradiation
2. 5x5 Gy + 3 cycles of consolidation chemotherapy

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# Response evaluation 11 weeks from RT commencement



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# Number of patients needed

Expected cCR rate in intermediate risk cancer: 10%

**140** patients are needed assuming 95% confidence interval  $\pm 5\%$

Expected cCR rate in advanced cancer: 5%

**75** patients are needed assuming 95% confidence interval  $\pm 5\%$

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Thank you for your attention.

I would welcome all critical remarks aimed at improving the protocol.

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