

# comparison between a bladder sparing approach and a radical cystectomy in patients with a non-metastasized muscle invasive bladder carcinoma

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON25055

### Source

Nationaal Trial Register

### Brief title

CRAC study

### Health condition

blaaskanker, spierinvasief  
bladder cancer, muscle invasive

## Sponsors and support

**Primary sponsor:** Amsterdam UMC, AMC

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

## Intervention

## Outcome measures

### Primary outcome

1 - comparison between a bladder sparing approach and a radical cystectomy in patien ... 13-05-2025

Disease free survival

## **Secondary outcome**

toxicity

costs

bladder preservation rate

Qol

## **Study description**

### **Background summary**

A bladder sparing treatment with radiochemotherapy or brachytherapy in patients with non-metastasised muscle invasive bladder carcinoma leads to comparable disease free survival and overall survival rates compared to radical cystectomy in non-randomised comparative retrospective studies. In over 70% of patients the bladder and its function can be preserved with bladder sparing treatments. However, a radical cystectomy is still considered as standard treatment by the lack of randomized controlled trials. It is very unlikely that such a trial will be conducted. Prospective matched control studies are second best in the comparison of outcome between both treatment. It is likely that medical costs, toxicity and quality of life will be better in the sparing approach arm, but again not previously prospectively analyzed.

### **Study objective**

A bladder sparing approach results in comparable disease free survival, overall survival with less toxicity, less costs and a high functional bladder preservation rate compared to a radical cystectomy.

### **Study design**

DFS at 2 and 5 years

### **Intervention**

NA

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

muscle invasive urothelial cell carcinoma of the bladder

T2-4aN0M0

curative intend

### Exclusion criteria

No previous RT

multifocal disease

## Study design

### Design

Study type: Observational non invasive

Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	25-11-2018
Enrollment:	1000
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	13-07-2018
Application type:	First submission

## 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
NTR-new	NL7159
NTR-old	NTR7358
Other	ZonMW project. : 843004124

## Study results