Reducing costs of surveillance of patients with non-muscle invasive bladder cancer.

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1) To prove that it is possible to safely reduce the number of invasive cystoscopies during follow-up (FUP) of patients with NMIBC with a low/intermediate risk of recurrence or progression. 2) To prove that addition of urine tests to the follow-up...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational non invasive

Summary

ID

NL-OMON44747

Source
ToetsingOnline

Brief title
URICA II

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Bladder and bladder neck disorders (excl calculi)

Synonym
Non-muscle invasive bladder cancer, superficial bladder cancer

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Cystoscopy, Non-muscle invasive bladder cancer (NMIBC), Recurrence tumor, Urine tests

Outcome measures

Primary outcome

- 15% more recurrences detected in the maximal care arm in patients in the

low/intermediate risk group.

- Proof that in the optimal care arm (intended to be the future follow-up

procedure) is safe regarding detected versus missed recurrences.

- Calculation of % of cystoscopies that would be unnecessary in the future.

- Cost-effectiveness of this strategy.

Secondary outcome

- 15% more recurrences detected in patients with a primary high-risk tumor.

- Indication that these are of lower stage.

- Cost-effectiveness.

Study description

Background summary

Cancer of the urinary bladder is the fifth most common cancer in the western world. Bladder tumors present either as non-muscle-invasive bladder cancer (NMIBC) or as muscle-invasive bladder cancer (MIBC). Over 60% of patients with NMIBC develop multiple recurrences and they are at risk for progression to MIBC. The need to monitor these patients, often for the rest of their life, makes bladder cancer the costliest cancer per patient. On average patients have 20 cystoscopies in the first 10 years of follow-up. We estimate that between 2-4 million cystoscopies are carried out yearly in the EU and USA. In the previous decade we have demonstrated that assays for tumor-associated DNA changes can detect recurrences in cells obtained from voided urine. The prospective trial represents the pivotal step to ensure that urine testing is

taken up in the guidelines of the EAU (European Association of Urology) and in the regular health care system.

Study objective

1) To prove that it is possible to safely reduce the number of invasive cystoscopies during follow-up (FUP) of patients with NMIBC with a low/intermediate risk of recurrence or progression.
2) To prove that addition of urine tests to the follow-up of patients with NMIBC at a high risk of recurrence and progression leads to earlier detection of potentially dangerous recurrences.

Study design

This will be a multicenter two-armed prospective randomized clinical trial (RCT).

Study burden and risks

Included patients are asked to provide two urine samples up to one month before each regular cystoscopy. The samples are to be sent by mail to the laboratory at Erasmus MC. There are no extra costs for the patients. The maximal number of these events is 12 during the duration of the project. There are no extra visits to the hospital.

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) (Previous) primary NMIBC
2) Currently under surveillance for possible recurrent disease
3) Monitored by the urology patient archives in the participating hospitals

Exclusion criteria

1) Patients upgraded at reTUR to MIBC
2) Patients presenting with MIBC
3) Patients below 21 years of age. ;After the initial TUR, a second TUR (reTUR) is recommended for patients with pT1 tumors. This is to establish whether resection was radical and when there is remaining tumor whether the tumor is muscle-invasive. In the latter case these patients will be excluded because they do not belong to the NMIBC category

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-02-2015
Enrollment:	435
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-10-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL50879.078.14