Reduceren van de4 kosten van de controle van patienten met niet-spier-invasief blaaskanker

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1) Surveillance of patients with a urine test, followed by cystoscopy only when the urine test is positive, results in detection of a the same or a higher number of recurrences and is cost-effective and 2) urine diagnostics contribute to earlier...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28752

Bron
Nationaal Trial Register

Verkorte titel
URICA II

Aandoening

Bladder Cancer
bladder cancer, non-muscle invasive, surveillance, cystoscopy, urine test

Blaaskanker, oppervlakkig blaaskanker, controles, cystoscopie, urine test

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: ZONMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

15% extra recurrences detected in maximal care arm;
40% percentage decrease in cystoscopies in optimal care arm;
costs of optimal care vs classic care: 4000 euro less;

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVE(S) / RESEARCH QUESTION(S): 1) to prove that it is possible to safely reduce the number of invasive cystoscopies during FUP of patients with non-muscle invasive bladder cancer (NMIBC) with a low/intermediate risk of recurrence or progression and 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.

HYPOTHESIS: 1) Surveillance of patients with a urine test, followed by cystoscopy only when the urine test is positive, results in detection of a the same or a higher number of recurrences and is cost-effective and 2) urine diagnostics contribute to earlier detection of recurrences in patients at high-risk for recurrences or progression to potentially lethal MIBC (high-risk group)

STUDY DESIGN: This will be a multicenter two-armed prospective RCT. In the maximal care arm urine tests are performed prior to cystoscopy such that the urologist is aware of the outcome. In the classic care arm conventional follow-up is carried out, urines are analyzed as in the maximal care arm, but their outcome is not communicated. The data from both arms in terms of detected and missed recurrences will be used to calculate the performance of a virtual third optimal care arm in which follow-up is by urine tests with a cystoscopy only when the urine test is positive for patients entered with NMIBC in the low/intermediate groups. The data from classic and maximal care arms will be compared for the patients entered with high-risk NMIBC to determine whether more recurrences are detected in the maximal care arm and whether these recurrences are of lower stage.

STUDY POPULATION: patients under surveillance for recurrences after a NMIBC primary tumor who are 21 years or older.

INTERVENTION: urine analysis.

OUTCOME MEASURES: % extra recurrences detected in maximal care arm, % decrease in cystoscopies in optimal care arm, costs of optimal vs classic care, lower stage recurrences in high-risk group.

SAMPLE SIZE: 435 patients, 2*1418 urines, 449 recurrences

ANTICIPATED HEALTHCARE EFFICIENCY GAIN: > 40% fewer cystoscopies, 4000 € cost reduction per patient in the low/intermediate risk groups. Earlier detection of recurrences in high-risk group and stage regression, at additional costs.

TIME SCHEDULE: 36 months. Inclusion of patients under surveillance in the first 3 months, new patients thereafter. In the next 27 months urines will be sampled and analyzed. At the end 6 months are available to provide sufficient follow-up and for data analysis.

KEY WORDS: bladder cancer, non-muscle invasive, surveillance, cystoscopy, urine test

Doel van het onderzoek

1) Surveillance of patients with a urine test, followed by cystoscopy only when the urine test is positive, results in detection of a the same or a higher number of recurrences and is cost-effective and 2) urine diagnostics contribute to earlier detection of recurrences in patients at high-risk for recurrences or progression to potentially lethal MIBC (high-risk group)

Onderzoeksopzet

The intervention studied is the biomarker analysis of two urine samples from a patient taken a month prior to cystoscopy. In the maximal care arm the outcome of the urine tests will be communicated to the urology department of the relevant hospital in such a way that the urologist who performs the cystoscopy is aware of the test result: positive or negative. A positive urine test outcome means that one or both urine tests were positive and a negative outcome when both tests were negative. Patients with a negative urine test and a negative cystoscopy outcome will be scheduled for a next cystoscopy according to the guidelines. When the urine test is positive or negative in combination with a positive cystoscopy, the tumor will be resected and the patient will be scheduled for a next cystoscopy according to the guidelines. If the urine test is positive and cystoscopy is negative, the patient will be asked to return for another cystoscopy 3 months later. In these cases urine testing is again performed before the cystoscopy. When a tumor is detected at this cystoscopy the patient will be scheduled for TUR. If both tests are negative, the patient will return to a follow-up schedule according to the guidelines for his/her risk situation. If the urine tests are again positive and cystoscopy is negative, the patient will be scheduled for a CT/ureterorenoscopy/retrograde pyelography to examine the upper urinary tract. When positive, the tumor will be resected, when negative, the patient will return to a follow-up schedule according to the guidelines for his/her risk situation.

In the classic surveillance arm, urine samples will be obtained also before cystoscopy as in the maximal care arm. The urine tests will be performed at a convenient moment and the results will not be communicated to the urologist. A positive cystoscopy will be followed by a TUR. The MD/PhD student will regularly visit each hospital to obtain the data and include new patients. She/he will further provide follow-up schemes according to the EAU guidelines to be entered in each patient’s file. The urologist/resident can use these to mark his/her decisions

and this can then easily been extracted by the MD/PhD student for the database.
Follow up intervals in both arms of the study will be according to the EAU guidelines and we will enforce this in the different hospitals. In a limited number of cases (suspicion of CIS), fluorescence guided or narrow band cystoscopy will be carried out in the Amphia and St Franciscus hospitals. These cases will be included as a separate group, and analyzed separately.

Onderzoeksproduct en/of interventie

Cystoscopy is an invasive diagnostic procedure. Urine analysis can replace part of the cystoscopies.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

patients under surveillance for recurrences after a NMIBC primary tumor

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

under 21 years of age

patients upgraded at reTUR to NMIBC

Patients presenting with MIBC

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	05-01-2015
Aantal proefpersonen:	450
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-12-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6709
NTR-old	NTR6879
Ander register	ZONMW : 837001502

Resultaten

Samenvatting resultaten
NA