Molecular diagnostics of bladder cancer.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON30884

Source
ToetsingOnline

Brief title
URICA

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Bladder and bladder neck disorders (excl calculi)

Synonym
bladder cancer, urothelial carcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bladder cancer, molecular techniques, urine

Outcome measures

Primary outcome

The results of either no mutation or a mutation in FGFR3.

There are 11 mutations known in FGFR3, which are analyzed simultaneously.

Secondary outcome

n.v.t.

Study description

Background summary

Recent independent studies have shown that 85% of the non-muscle invasive urothelial carcinomas contain a mutation in the Fibroblast Growth Factor Receptor-3 (FGFR3) gene. We developed a SnaPshot assay to detect this mutation in DNA derived from urine samples. Eventually our aim is to detect recurrences with this assay at an early stage and hereby to reduce the amount of cystoscopies carried out. Additionally this will reduce physical and mental distress in patients caused by a cystoscopy.

Study objective

Previous research demonstrates that in some cases, where the tumor of the patient contains a mutation in FGFR3, the mutation can not be detected in urine derived from the same patient. Our hypothesis states that this urine does not contain any tumor cells at the moment of collection, leading to an impaired detection of FGFR3 in urine samples.
In order to test the hypothesis urine (collected throughout the whole day) derived from bladder cancer patients should be collected for multiple days prior to being operated. This way the optimal moment for urine collection can be determined.

Study design

Patients, who are scheduled for a transurethral resection of a bladder tumor, are selected. Ten days prior to the operation all urine of these patients is collected and picked up twice a day, for example at 9:00 and 16:00 o'clock. DNA is isolated from the urine samples and used for FGFR3 mutation analysis.

Study burden and risks

Patients should collect all urine for ten days.
There are no risks associated with participation in this study.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients diagnosed with bladder cancer

Exclusion criteria

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Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-10-2007
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	26-09-2007
Application type:	First submission
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	NL19144.078.07