

Explorable study - possible explanation for the reduced risk of urethral recurrence after Hautmann neobladder for bladder cancer.

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Objective of this study is to map the possible differences in immunostatus between a urethra in patients with a Hautmann neobladder and a normal urethra in patients without (a history of urogenital) malignancy; to find clues for the decreased risk...

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

Summary

ID

NL-OMON31928

Source

ToetsingOnline

Brief title

urethral recurrence after Hautmann neobladder

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Urethral disorders (excl calculi)

Synonym

tumor in urethra, urethral tumor

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bladder cancer, cystectomy, Hautmann neobladder, urethral recurrence

Outcome measures

Primary outcome

the immunostatus of the urethra.

Secondary outcome

not applicable

Study description

Background summary

In bladder cancer recurrence is a major problem. These recurrences can be located in the upper urinary tract, the urethra, local or at distant sites.

Multiple factors are associated with recurrence in the urethra. One of these factors is the type of bladder diversion; the risk of urethral recurrence after Hautmann neobladder is decreased compared to the non-orthotopic bladder diversions. No explanation is known for this difference.

The most successful treatment of non-muscle invasive bladder cancer is a specific immunotherapy with BCG bladder instillations. Although the exact mode of action remains to be solved, an infectious reaction of the bladder wall plays a crucial role in the effect of BCG. Likewise, we hypothesized that the chronic low grade infection in an ileal neobladder might protect the urethra against recurrent UCC. Therefore, infection parameters in urethral biopsies might shed light on this theory.

Study objective

Objective of this study is to map the possible differences in immunostatus between a urethra in patients with a Hautmann neobladder and a normal urethra in patients without (a history of urogenital) malignancy; to find clues for the

decreased risk of urethral recurrence in patients with a Hautmann neobladder.

Study design

Explorable, single centre study (Radboud University Nijmegen Medical Center)

In 10 patients with a Hautmann neobladder we'll take two supervicial urethral biopsies during a cystoscopy (part of routine oncological follow-up) on the outpatient department.

In 10 patients two supervicial urethral biopsies are taken during the transurethral surgery for which they are planning.

Study burden and risks

Risks: bleeding from the biopsy lesion and urethral pain.

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

group 1:

- patients who underwent a cystectomy + Hautmann neobladder for bladder cancer
- since at least 1 year ago
- patients must be over 18 years of age;group 2:
- patients who are planned for TURP, bladder neck incision or urethrotomy (no malignancy).
- patients must be over 18 years of age

Exclusion criteria

group 1:

- patients who underwent cystectomy with a type of urinary diversion other than Hautmann neobladder.
- use of anticoagulant drugs;group 2:
- history of urological malignancy
- use of anticoagulant drugs

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 15-04-2008

Enrollment: 20

Type: Anticipated

Ethics review

Approved WMO

Application type:

First submission

Review commission:

CMO regio Arnhem-Nijmegen (Nijmegen)

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

NL22226.091.08