To investigate whether rinsing the bladder with chemotherapy right before an operation that removes the kidney and ureter because of a malignant tumor is effective to reduce the risk of a subsequent bladder tumor

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24959

Source
NTR

Brief title
REBACARE

Health condition

Bladder cancer (blaaskanker), chemotherapy (chemotherapie), nephro-ureterectomy (nefro-ureterectomie), upper urinary tract (hogere urinewegen), urothelial carcinoma (urotheelcelcarcinoom)

Sponsors and support

Primary sponsor: Erasmus university Medical Center
Source(s) of monetary or material Support: IKNL, KWF

Intervention

Outcome measures

Primary outcome

The bladder cancer recurrence rate up to two years following surgery.

Secondary outcome

- Compliance rate;

- 2-year overall survival (OS), cancer-specific survival (CSS) and recurrence-free survival (RFS);

- Toxicity of the regime (CTCAE);

- Quality of life (EQ5D-5L, EORTC QLQ-C30);

- Calculation of costs of a single neoadjuvant instillation with Mitomycin;

- Molecular characterization of the upper urinary tract urothelial carcinoma and subsequent urothelial carcinoma of the bladder.

Study description

Background summary

A prospective, observational, cohort study to investigate the effect of a single, preoperative intravesical instillation with Mitomycin immediately before nephroureterectomy or partial ureterectomy for a urothelial carcinoma of the upper urinary tract on the risk for developping a bladder cancer recurrence compared to a historical control group who received no intravesical instillation.

Study objective

A preoperative (<3 hours) intravesical instillation with Mitomycin will reduce the risk of a metachronous bladder tumor after radical nephroureterectomy or partial ureterectomy for urothelial carcinoma of the upper urinary tract.

Study design

T0 = screening for elegibility

T1 = inclusion, questionnaires (EQ5D-5L, EORTC QLQ-C30)

T2 = instillation, surgery, CTCAE

T3 = 1 month: postoperative controle and histology, CTCAE

T4 = 3 months: Cystoscopy, urine cytology, quistionnaires (EQ5D-5L, EORTC QLQ-C30)

T5 = 6 months: cystoscopy, urine cytology, CT urography, CT Thorax

T6 = 12 months: cystoscopy, urine cytology, CT urography, CT Thorax

T7 = 18 months: cystoscopy, urine cytology, CT urography

T8 = 24 months: cystoscopy, urine cytology, CT urography

Intervention

Intravesical instillation with Mitomycin within 3 hours before radical nephroureterectomy or partial ureterectomy.

Contacts

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Eligibility criteria

Inclusion criteria

- Histologically proven urothelial carcinoma of the upper urinary tract with or without concurrent carcinoma in situ (CIS only is allowed) or patients with a suspicion of a urothelial carcinoma of the UUT on CT-scan plus a urinary cytology sample showing high-grade

urothelial carcinoma;

-Patients planned to be treated either by partial ureterectomy or by a radical nephro-ureterectomy (open or laparoscopic) including a bladder cuff;

- Age ≥ 18 years;

- WHO perfomance status 0, 1 or 2;

- Negative pregnancy test in woman with childbearing potential;

- Written informed consent.

Exclusion criteria

- If pre-operative histology by biopsy shows aberrant histology of the UUT tumor of >50% (adenocarcinoma, small cell carcinoma, squamous cell carcinoma).

- History or presence of a malignant tumor or carcinoma in situ of the bladder.

- History of UUT urothelial carcinoma on the contralateral side or presence of bilateral UUT urothelial carcinoma.

- Known allergy against Mitomycin.

- Anticipated adjuvant intravesical treatment with chemo- or immunotherapy.

- Acute urinary tract infection at the time of inclusion as assessed by urinary culturing.

- Lymphadenopathy or distant metastases as assessed by preoperative CT-scan of thorax and abdomen.

- Any other concurrent severe or uncontrolled disease preventing the safe administration of intravesical Mitomycin.

- Breastfeeding woman.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2017
Enrollment:	170
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-06-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50424
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6361
NTR-old	NTR6545
CCMO	NL60919.078.17
OMON	NL-OMON50424

Study results