The efficacy of an antigenic marker lesion for the therapeutic effect in patients with multiple, Ta/T1, G1/G2, non-muscle invasive bladder cancer (NMIBC) treated with TUR followed by IL-2 instillation

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We like to demonstrate that treatment of non-muscle invasive bladder carcinoma with incomplete TUR and IL-2 is therapeutically more effective than treatment with complete TUR and IL-2.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON41468

Source
ToetsingOnline

Brief title
Incomplete TUR and IL-2

Condition

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

Synonym
non-muscle invasive bladder carcinoma; bladder cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Innovatiefonds Zorgverzekeraars Nederland;Novartis Pharma

Intervention

Keyword: Interleukin-2, marker tumour, non-muscle invasive bladder cancer, Trans-Urethral Resection

Outcome measures

Primary outcome

1. Tumour-free period after treatment

2. Percentage tumour-free patients 2 years after intervention

3. Percentage complete regressions of marker tumours 3 months after

intervention

Secondary outcome

1. Values of different immunological parameters (e.g. T-cel populations and

cytokine concentrations in the blood)

2. Quality of life after the intervention

Study description

Background summary

Non-muscle-invasive carcinoma of the bladder is usually treated with Trans Urethral Resection (TUR) followed by instillation of a chemotherapeuticum or an immunotherapeuticum. The tumour recurs in 30 - 85 % of the patients; the median tumour-free period is only about 5 months.

We have performed 2 phase II studies: incomplete TUR leaving a marker tumour of ca 1 cm (Krakau) and a study with complete TUR (Vilnius). In both studies the patients received IL-2 instillations after TUR. Patients treated with complete TUR had a median disease-free period of 5 - 6 months, whereas in patients

treated with incomplete TUR the median disease-free survival was more than 24 months.

These results led to the hypothesis that incomplete TUR followed by IL-2 instillations caused significantly better therapeutic effects than complete TUR followed y IL-2 instillations. This can be explained as a marker tumour (incomplete TUR) contains antigens that initiate the anti-tumour immune reaction; this initial immune reaction is, subsequently, stimulated by instilled IL-2

Study objective

We like to demonstrate that treatment of non-muscle invasive bladder carcinoma with incomplete TUR and IL-2 is therapeutically more effective than treatment with complete TUR and IL-2.

Study design

This is a randomised open clinical intervention study of 2 years. There are 2 groups: a test group treated with incomplete TUR and a control group treated with complete TUR

Intervention

Incomplete TUR, leaving a marker tumour that stimulates the therapeutic effect of IL-2 instillations

Study burden and risks

The test patients receive the same interventions as the control patients.
If our hypothesis is correct, then the test group will get significantly less recurrent bladder tumours than the control
group

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

Patients with the diagnosis multiple (< 10) resectable Ta(G1,2) or T1(G1,2) non-muscle invasive bladder carcinoma as diagnosed by pathological examination

Exclusion criteria

Excluded are patients with CIS, or a cancer type other than urothelial cell carcinoma, or with a second malignancy (except treated basal cell carcinoma of the skin), or a tumour in the prostatic urethra or in a diverticulum or in the upper urinary tract

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-05-2011
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-12-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2010-020397-42-NL
CCMO	NL32293.029.10