Feasibility of chemotherapy and regional hyperthermia in patients with intermediate/high risk non-muscle invasive transitional cell carcinoma of the bladder

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Primary objective: to study the feasibility and toxicity of the combination of intravesical chemotherapy with Mitomycin C and regional 70 MHz microwave therapySecondary objective: to develop a new bladder catheter with sufficient thermocouples to...

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

Summary

ID

NL-OMON32637

Source
ToetsingOnline

Brief title
chemohyperthermia in non invasive bladder cancer

Condition

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

Synonym
non invasive bladder cancer non invasive urothelial cell carcinoma of the bladder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: intravesical chemotherapy, locoregional hyperthermia, non-muscle invasive bladder cancer, pilot study

Outcome measures

Primary outcome

Toxicity will be measured using the Common Toxicity Criteria. With these

criteria immunological symptoms, constitutional symptoms and

renal/genitourinary symptoms can be categorized. If the treatment has to be

delayed two times in a row because of toxicity, treatment will be discontinued

Secondary outcome

Satisfying thermometry with the new bladder catheter

Study description

Background summary

Intermediate/high risk non-muscle invasive transitional cell carcinoma of the bladder has a high recurrence rate and considerable risk on progression despite intravesical chemotherapy and immunotherapy. Applying local hyperthermia in combination with intravesical Mitomycin C is a promising development. A higher thermal dose is expected using locoregional hyperthermia instead of local hyperthermia supported by hyperthermia treatment planning.
As there is a significant relation between thermal dose and response rate the clinical outcome will be improved.

The following protocol has been established in order to evaluate and compare the feasibility and safety of 70 MHz locoregional hyperthermia applied with concomitant Mitomycin C intravesically.

Study objective

Primary objective: to study the feasibility and toxicity of the combination of intravesical chemotherapy with Mitomycin C and regional 70 MHz microwave therapy

Secondary objective: to develop a new bladder catheter with sufficient thermocouples to measure accurately the temperature on the bladder wall.

Study design

This study is designed as a pilot study to evaluate the feasibility and toxicity of the combination of two well known treatments, in non-muscle invasive bladder cancer. When feasible, a phase II study will be started in which this treatment will be optimised by the application of new hyperthermia techniques. The expectation is that in this way higher tumor temperatures can be reached and therefore local tumor control can be improved.

Intervention

The intervention consists of 6 weekly courses of intravesical chemotherapy with MMC, 40 mg. MMC will be concomitantly given with locoregional 70 MHz microwave hyperthermia, given for 1 hour at a temperature of at least 41°C.
This induction phase will be followed by a maintenance period of 12 months during which 4 single courses of hyperthermia in combination with MMC will be given: at 3, 6, 9 and 12 months.

Study burden and risks

The conventional treatment of intermediate/ high risk non-muscle invasive bladder carcinoma is a TURB followed by intravesical therapy with either chemotherapy or immunotherapy. This is installed in the bladder with a standard bladder catheter. During this treatment hyperthermia is started. Because of this combination, treatment takes half an hour more. Hyperthermia can cause feelings of heat and discomfort. Cooling will be done with a fan and/or wet towels.
From previous studies we know that toxicity and risks are minimal when given hyperthermia to the pelvis. Side effects will be scored with the Common toxicity scale.
Higher temperatures may lead to less recurrences and therefor less progression of disease leading to a better overall survival.

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 intermediate/ high risk Ta-1 grade 3 or Ta-1 grade 2 recurrent or carcinoma in situ (CIS) non-muscle invasive transitional cell carcinoma of the bladder.

Exclusion criteria

*Intravesical (Mitomycin C) MMC during the last 12 months
*Bladder tumors other than transitional cel carcinoma
*Known allergy to MMC
*Small bladder volume; less than 100 cc measured by uroflowmetry
*Residual urine > 100 cc measured by ultrasound
*A history of muscle invasive carcinoma of the bladder
*Urinary incontinence
*Hip prosthesis
*Pacemaker

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2008
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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
CCMO	NL24042.018.08