a phase III randomised trial of intravesical chemotherapy vs thermo-chemotherapy in intermediate risk non-muscle invasive bladder cancer

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To compare standard treatment with intravesical chemotherapy with loco-regional thermo-chemotherapy in patients with an intermediate risk non-muscle invasive urothelial carcinoma of the bladder after complete transurethral resection of the tumour(s...

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

Summary

ID

NL-OMON39804

Source
ToetsingOnline

Brief title
CHIB study

Condition

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

Synonym
non-muscle invasive bladder cancer, superficial bladder cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: hyperthermia, intravesical Mitomycin C, NMIBC, randomised trial

Outcome measures

Primary outcome

1. Recurrence free survival

Secondary outcome

2. Progression rate

3. Toxicity

4. Functional bladder capacity

5. Quality of Life

Study description

Background summary

Standard treatment for non-muscle invasive bladder cancer is transurethral resection of all visible lesions (TURB). This establishes the diagnosis and allows pathologic analysis of the resected tumour specimen for tumour grade and depth of invasion. Despite this resection a recurrence is seen in 50 to 75% depending on the risk group of the tumour. However, progression into a muscle-invasive cancer is a much more threatening event and is seen in 20 to 30%. Prognosis of this group of patients is poor with an overall survival of 55% at 5 years.
Last decade, a number of studies have been conducted with intravesical Mitomycin C in combination with local Hyperthermia to reduce the number of recurrences with positive results. The combination of loco-regional hyperthermia and chemotherapy has
proven to have synergistic effects in the treatment of invasive cancer in pelvic organs. A pilot study of loco-regional thermo-chemotherapy in non-muscle invasive bladder cancer that was conducted in the AMC 2009-2011

appeared to be feasible and safe.

Study objective

To compare standard treatment with intravesical chemotherapy with loco-regional thermo-chemotherapy in patients with an intermediate risk non-muscle invasive urothelial carcinoma of the bladder after complete transurethral resection of the tumour(s).

Study design

A Phase III randomised trial.

Intervention

The intervention will be:
Arm 1 (standard arm): Following a complete resection of the bladder tumour(s): 6 weekly courses with intravesical chemotherapy using Mitomycin C 40 mg followed by a maintenance scheme during 1 year of 1 instillation to be given at months 3, 6, 9 and 12.

Arm 2 (experimental arm): Following a complete resection of the bladder tumour(s): 6 weekly courses of intravesical chemotherapy using Mitomycin C 40 mg in combination with loco-regional (70MHz) microwave hyperthermia, followed by a maintenance scheme during 1 year of 1 instillation to be given at month 3, 6, 9 and 12.

Study burden and risks

Standard therapy for non-muscle invasive bladder cancer is trans urethral resection of the tumor followed by Mitomycin C instillations. Patients can go home after the Mitomycin C is instilled into the bladder and urinate the contents at home. In arm B, the experimental arm, patients will undergo directly after the instillation the hyperthermia treatment that takes 2 hours. During this treatment patients experience heat in the pelvis that can result in sweating. Most of the time this can easily be solved by cooling with a fan and /or wet towels. In our fase I study toxicity was limited to grade1 (some discomfort that can easily be solved) and occasionaly grade 2 toxicity (bladder spasms).
Hyperthermia treatment will be given 10 times during 1 year. After this period patient will be in the follow up.
To measure quality of life 2 validated questionary's have to be filled out and patient have to undergo some additional test to measure the bladder capacity. These tests are not invasive.
The addition of hyperthermia can reduce the number of recurrences and perhaps the number of progression. In this case less interventional diagnostics is

needed and in worse cases may even prevend a cystectomy.

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 an intermediate risk non-muscle invasive urothelial carcinoma of the bladder.
* WHO performance status of 0-2
* Life expectancy of more than 24 months
* Written informed consent
* Age * 18 years

Exclusion criteria

* Intravesical mitomycin C during the last 6 months
* Previous treatment with Bacillus Calmette Guerin
* Bladder tumours other than urothelial carcinoma
* Known allergy to MMC
* Small bladder volume; less than 100 cc
* Urinary incontinence
* Hip prosthesis
* Pacemaker/ICD
* Incapability of inserting catheters for thermometry or measuring temperatures in bladder or anal canal
* Inability to comply with the treatment protocol

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):	08-09-2015
Enrollment:	212
Type:	Actual

Ethics review

Approved WMO

Date:	03-03-2015
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

ID: 21384
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL40086.018.12
OMON	NL-OMON21384