Feasibiblity of treatment with heat in combination with intravescial chemotherapy in the treatment of non-muscle invasive bladder cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24485

Source
NTR

Brief title
CHIB study

Health condition

intermediate risk/high risk non-muscle invasive bladder carcinoma
intermediate/hoge risico niet-spier invasief blaascarcinoom

Sponsors and support

Primary sponsor: AMC
Source(s) of monetary or material Support: fonds= verrichter=sponsor

Intervention

Outcome measures

Primary outcome

Feasibility en toxicity.

Secondary outcome

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

Study description

Background summary

Feasibility of treatment with regional hyperthermia with 70 MHz and intravesical chemotherapy in intermediate/high risk non-muscle invasive bladder carcinoma.

The Netherlands.

Study objective

The addition of regionale hyperthermia to treatment with intravesical chemotherapy with mitomycin C is feasible and not toxic.

Study design

Wk 1-6, wk 12, wk 24, wk 36, wk 48.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with an intermediate or high risk non-muscle invasive transitional cell carcinoma of the bladder according to the EAU definition; Ta-1 grade 3 or Ta-1 grade 2 recurrent or Carcinoma in situ;

2. A complete transurethral resection has to be performed within 3-6 weeks prior to study treatment. Complete tumour eradication must be verified by taking biopsies from suspected areas. The treatment session should begin 3-8 weeks after the initial TURB;

3. WHO performance status of 0-2;

4. Life expectancy of more than 24 months;

5. Written informed consent.

Exclusion criteria

1. Intravesical MMC during the last 12 months;

2. Bladder tumors other than transitional cel carcinoma;

3. Known allergy to MMC;

4. Small bladder volume; less than 100 cc measured by uroflowmetry;

5. Residual urine > 100 cc measured by ultrasound;

6. A history of muscle invasive transitional cell carcinoma of the bladder;

7. Urinary incontinence;

8. Hip prosthesis;

9. Pacemaker.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2009
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	29-09-2010
Application type:	First submission

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
NTR-new	NL2429
NTR-old	NTR2538
Other	MEC AMC : 08/196
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A