Lotingsstudie bij oppervlakkige blaaskanker met blaasspoelingen met of zonder warmtebehandeling

No registrations found.

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

Summary

ID

NL-OMON21384

Source
NTR

Brief title
CHIB study

Health condition

intermediate risk non muscle invasive bladder cancer, Mitomycin C, intravesical chemotherapy, locoregional hyperthermia, chemohyperthermia, recurrence free survival
intermediair risico niet spier invasief blaas carcinoom, Mitomycine C, intravesicale chemotherapie, locoregionale hyperthermie, chemohyperthermie, recidief vrije survival

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: KWF funding for datamanagement

Intervention

Outcome measures

Primary outcome

To describe the effect of additional treatment with loco-regional 70-90 MHz hyperthermia to the standard treatment with intravesical MMC on the recurrence rate in patients with an intermediate risk non-muscle invasive urothelial carcinoma of the bladder.

Secondary outcome

To describe the effect of the additional treatment with locoregional hyperthermia 70-90 MHz on tumour progression, acute toxicity, functional bladder capacity and quality of life.
Study design: A Phase III randomised trial.
Study population: Patients with intermediate risk non-muscle invasive urothelial

Study description

Background summary

In treatment of intermediate risk non-muscle invasive bladder cancer local recurrence rate remains high even after intravesical chemotherapy.
The efficacy of a locoregional 70 MHz hyperthermia will be investigated in this study in combination with intravesical chemotherapy.

Study objective

locoregional 70 MHz hyperthermia in combination with intravesical chemotherapy will improve recurrence free survival in comparison with intravesical chemotherapy alone in intermediate risk non muscle invasive bladder carcinoma

Study design

at 3,6,9,12, 2nd and 3rd year every six months TURT, Cystoscopy, Urinanalysis, Uroflowmetry, Residual urine volume determination, Upper urine tract imaging, Voiding diary, QoL EORTC QLQ-C30, QoL EORTC BSL24, Toxicity score (CTC 4.0) will be measured.

Intervention

The intervention will be:

Arm 1 (standard arm): Following a complete resection of the bladder tumour(s): an induction period of 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): an induction period 6 weekly courses of intravesical chemotherapy using Mitomycin C 40 mg in combination with locoregional (70-90 MHz) microwave hyperthermia, followed by a maintenance scheme during 1 year of 1 instillation to be given at months 3, 6, 9 and 12.

Contacts

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Eligibility criteria

Inclusion criteria

Patients with an intermediate risk non muscle invasive urothelial carcinoma of the bladder. For determination of the risk group the EAU scoring system will be used
performance status of 0 to 2

Life expectancy of more than 2 years

Written informed consent

Minimum age of eightteen years

Exclusion criteria

Intravesical MMC during the last 6 months

Bladder tumours other than urothelial carcinoma

Known allergy to MMC

Previous treatment with Bacillus Calmette Guérin

Small bladder volume less than 100 cc

Residual urine more than 200 cc measured by ultrasound

A history of muscle invasive urothelial carcinoma of the bladder

Urinary incontinence

Untreatable urine tract infection

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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2015
Enrollment:	212
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39804
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5636
NTR-old	NTR5751
CCMO	NL40086.018.12
OMON	NL-OMON39804

Study results

Summary results

A Systematic Review of Regional Hyperthermia Therapy in Bladder Cancer. Thomas Andrew Longo, Ajay Gopalakrishna, Matvey Tsivian, Megan Van Noord, Coen R Rasch, Brant Inman, Debby Geijsen.
International Journal of Hyperthermia. 2016 in press.

Combining Mitomycin C and Regional 70 MHz Hyperthermia in Patients with Nonmuscle Invasive Bladder Cancer: A Pilot Study.
Geijsen ED, de Reijke TM, Koning CC, Zum Vörde Sive Vörding PJ, de la Rosette JJ, Rasch CR, van Os RM, Crezee J.
J Urol. 2015 Nov;194(5):1202-8.

Novel multisensor probe for monitoring bladder temperature during locoregional chemohyperthermia for nonmuscle-invasive bladder cancer: technical feasibility study.
Cordeiro ER, Geijsen DE, Zum Vörde Sive Vörding PJ, Schooneveldt G, Sijbrands J, Hulshof MC, de la Rosette J, de Reijke TM, Crezee H.
J Endourol. 2013 Dec;27(12):1504-9