

Lotingsstudie bij oppervlakkige blaaskanker met blaasspoelingen met of zonder warmtebehandeling

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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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21384

Bron

NTR

Verkorte titel

CHIB study

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam

Overige ondersteuning: KWF funding for datamanagement

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

at 3,6,9,12, 2nd and 3rd year every six months TURT, Cystoscopy, Urinalysis, 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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 eighteen years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-09-2015
Aantal proefpersonen: 212
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 15-02-2016
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39804
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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 Geijssen.

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.

Geijssen 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, Geijssen 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