Onderzoek naar de uitkomst van chemotherapie gevolgd door een lymfeklieroperatie en een gecombineerde behandeling van chemotherapie met uitwendige bestraling voor hoog-risico spier-ingroeiend blaaskanker (CHEMORAD-TRIAL)

No registrations found.

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

Summary

ID

NL-OMON27865

Source
Nationaal Trial Register

Brief title
CHEMORAD-TRIAL

Health condition

Bladder cancer, locally advanced disease, node positive disease, chemotherapy, lymph node dissection, chemoradiation

Sponsors and support

Primary sponsor: The Netherlands Cancer Institute-Antoni van Leeuwenhoek Hospital
Postbus 90203, 1006 BE, Amsterdam

The Netherlands
Source(s) of monetary or material Support: None, funding request pending

Intervention

Outcome measures

Primary outcome

- Bladder-preservation rate

- No evidence of disease at 12 months followup

Secondary outcome

- Recurrence rates (local and distant)

- Toxicity rates following induction chemotherapy

- Complication rates following ePLND

- Toxicity rates following chemoradiation

- Quality of Life (EuroQol EQ-5D-3L; SF-12)

- Disease specific survival

- Recurrence free survival

- Genetic biomarkers

Study description

Background summary

Systemic treatment with cisplatin-based combination chemotherapy has been shown to improve the outcome of patients presenting with locally advanced muscle-invasive bladder cancer and patients with lymph node positive disease, albeit at best an absolute 6.5% increase in overall survival at 5-years follow-up[1-6]. Aims of the present study are: to evaluate the bladder preservation rate after chemoradiation, and furthermore assessment of the toxicity and complications of induction cisplatin-based combination chemotherapy followed by pelvic lymph node dissection (ePLND) and chemoradiation.

Study objective

After chemoradiation the bladder-preservation rate after two years followup will be around 85%

Study design

Quality of Life assessment will be performed using validated questionnaires: EuroQol EQ-5D-3L and SF-12. These questionnaires will be submitted at the following moments: T0 (entry of study); T6 (after 6 months); T12 (after 12 months); T24 (after 24 months).

Intervention

-Neoadjuvant chemotherapy

-Pelvic lymph node dissection

-Chemoradiation

Contacts

Public
Department of Urology UMC Utrecht

R.P. Meijer
Utrecht
The Netherlands
Scientific
Department of Urology UMC Utrecht

R.P. Meijer
Utrecht
The Netherlands

Eligibility criteria

Inclusion criteria

-Signed written informed consent

-Locally advanced urothelial carcinoma of the bladder (cT3-T4) or any cT-stage with

cytologically or histologically proven node positive urothelial carcinoma (or positive FDG/PET-CT-scan with suspect lymph nodes, including supraregional retroperitoneal lymph nodes below the diaphragm.

-Renal function: Creatinin clearance ¡Ý 50 mL/min (calculated) and serum creatinin ¡Ü1.5 x UNL.

-Karnofsky performance 70

Exclusion criteria

-Distant metastases (M+)

-Severe bladder symptoms (necessitating cystectomy).

-Bilateral hydronefrosis.

-Persisting hydronephrosis after induction chemotherapy (necessitating cystectomy). A temporary nefrostomy is indicated during chemotherapy.

-Previous radiation therapy on pelvic region

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-09-2015
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	NL5247
NTR-old	NTR5504
Other	NL51464.031.15 : M15CRB

Study results