Identification of muscle-invasive bladder cancer patients who will not benefit from neoadjuvant chemotherapy using circulating tumor cells.

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Patients without detectable CTCs will not benefit from neoadjuvant chemotherapy.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23413

Bron
Nationaal Trial Register

Verkorte titel
Cirguidance

Aandoening

muscle-invasive bladder cancer, circulating tumor cells, neoadjuvant chemotherapy

spierinvasieve blaaskanker, circulerende tumorcellen, neoadjuvante chemotherapie

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint for this study will be the 2-year overall survival rate in nonmetastatic MIBC patients without
detectable CTCs treated with radical local treatment without prior neoadjuvant chemotherapy.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Non-metastatic muscle-invasive bladder cancer (MIBC) is a potential lethal disease as half of the patients develop metastases after curative treatment. Neoadjuvant chemotherapy followed by radical treatment gives a statistically significant, though limited survival benefit (hazard ratio 0.84 (95% CI, 0.72-0.99) at 10 years). However, as neoadjuvant chemotherapy can be accompanied by severe toxicity, physicians are reluctant to embed neoadjuvant chemotherapy leading to different treatment approaches across centers. Identification of patients who will and who will not benefit from neoadjuvant chemotherapy is therefore of great clinical relevance.

Objective of the study:

Primary study objective is to prospectively assess whether the presence of CTCs in the peripheral blood of nonmetastatic MIBC patients can identify patients with such a good prognosis not justifying neoadjuvant chemotherapy.

Secondary study objectives include the association of CTC-positivity or negativity with cancer-specific survival, relapsefree
survival, local relapse-free survival and metastasis-free survival, as well as assessing the prognostic value of a 20-
gene expression profile in non-metastatic MIBC patients and its added value to a CTC count.

Study design:

Prospective, open study.

Study population:

Patients with stage T2-T4aN0-1M0 urothelial carcinoma of the bladder who are candidate for radical local treatment (radical cystectomy).

Primary study parameters/outcome of the study:

The primary endpoint for this study will be the 2-year overall survival rate in nonmetastatic MIBC patients without
detectable CTCs treated with radical local treatment without prior neoadjuvant chemotherapy.

Secundary study parameters/outcome of the study:

Secondary endpoints include 2-year overall survival in the remaining patients and cancer-specific survival, relapse-free
survival, local relapse-free survival and metastasis-free survival for all the patients. In addition, the expression pattern of the 20-gene panel is also a secondary endpoint.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
In all patients, 10 mL blood for CTC enumeration will be drawn at baseline during another blood draw that is already
required for standard care. It is hypothesized that patients without detectable CTCs will not benefit from neoadjuvant chemotherapy, sparing this
particular group of patients from a toxic and expensive treatment.

Doel van het onderzoek

Patients without detectable CTCs will not benefit from neoadjuvant chemotherapy.

Onderzoeksopzet

- 2-year overall survival rate in nonmetastatic MIBC patients without
detectable CTCs treated with radical local treatment without prior neoadjuvant chemotherapy.

- 2-year overall survival in the remaining patients and cancer-specific survival, relapse-free survival, local relapse-free survival and metastasis-free survival for all the patients.

Onderzoeksproduct en/of interventie

In all patients, CTCs will be enumerated. If no CTCs are detected, the patient will proceed to undergo local radical treatment (radical cystectomy) and will not receive neoadjuvant chemotherapy. In the case CTCs are detected, patients may undergo neoadjuvant chemotherapy followed by radical local treatment, dependent on the local guidelines.

Contactpersonen

Publiek

Erasmus MC
Dept. Urology
Room Na-1715
P.O. Box 2040
J.L. Boormans
Rotterdam 3000 CA
The Netherlands
+31-(0)10-704 12 32

Wetenschappelijk

Erasmus MC
Dept. Urology
Room Na-1715
P.O. Box 2040
J.L. Boormans
Rotterdam 3000 CA
The Netherlands
+31-(0)10-704 12 32

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Histopathologically confirmed muscle-invasive urothelial carcinoma of the bladder.

- Clinical stage T2-T4a N0-N1 bladder cancer.

- Candidate for radical local treatment consisting of radical cystectomy.

- Age 18 years or older.

- Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Muscle-invasive bladder cancer other than urothelial carcinoma (adenocarcinoma, squamous cell carcinoma, small cell carcinoma, neuro-endocrine tumor).

- History of other malignant disease with a tumor-free interval of less than 5 years.

- Known or suspected coincidental prostate cancer.

- Metastatic disease at staging, as assessed by a CT-scan of thorax and abdomen.

- Local or systemic adjuvant treatment after radical cystectomy.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	260
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-08-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 45144
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3954
NTR-old	NTR4120
CCMO	NL44847.078.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON45144

Resultaten

Samenvatting resultaten
N/A