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

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON45144

Source
ToetsingOnline

Brief title
CTCs to guide neoadjuvant chemotherapy in bladder cancer.

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Bladder and bladder neck disorders (excl calculi)

Synonym
muscle invasive bladder cancer, muscle invasive bladder carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

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

Outcome measures

Primary outcome

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.

Secondary outcome

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.

Study description

Background summary

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.

Study objective

Primary study objective is to prospectively assess whether the presence of CTCs in the peripheral blood of non-metastatic 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, relapse-free 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.

Intervention

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.

Study burden and risks

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.

Contacts

Public
Erasmus MC

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 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.
- Signed informed consent

Exclusion criteria

- 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 * 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.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2013
Enrollment:	320
Type:	Actual

Ethics review

Approved WMO Date:	06-08-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-06-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-10-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23413
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44847.078.13
Other	NTR TC4120