Pre-BladParadigm - the effect of diagnostic transurethral bladder tumor resection (TURBT) on the level of circulating tumor cells (CTCs) in the blood of patients suspected of muscle invasive bladder cancer

Published: 17-06-2021
Last updated: 04-04-2024

To validate the suggestion that transurethral resection of bladder tumors in patients with suspected muscle invasive bladder cancer can lead to circulating tumor cells.

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-OMON50772

Source
ToetsingOnline

Brief title
Pre-BladParadigm

Condition

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

Synonym
Bladder cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bladder cancer, Circulating tumor cells, Transurethral resection

Outcome measures

Primary outcome

Number of CTCs in 7.5 ml of blood taken from a peripheral vein before vs. after

TURBT. In the second blood tube, CTCs will be isolated to check for metastatic

potential by means of RNA expression.

Secondary outcome

None

Study description

Background summary

Patients who suffer from muscle invasive bladder cancer (MIBC) are commonly treated with radical cystectomy (RC), sometimes in combination with neoadjuvant chemotherapy (NAC). However, the 5-year survival rate for these patients remains poor, approximately 50%, and this has not changed during the last decades. Patients are often diagnosed with metastases within two years after the initial surgery which suggests that micrometastases might already be present at the time of surgery. This might be due to the preoperative procedure used in the diagnosis of MIBC patients, namely transurethral resection of the bladder tumor (TURBT). During TURBT the bladder is rinsed with a fluid under high pressure while it is attempted to remove the tumor completely. This is quite exceptional in the management of cancer. In other cancer types, the diagnosis is only made by a biopsy plus imaging before radical treatment. The TURBT procedure was found to be capable of damaging the bladder wall, and blood and lymphatic vessels, which might push the tumor cells into the circulation

leading to the formation of micrometastases. Furthermore, the pressure induced in the bladder during TURBT is higher than the venous pressure in the surrounding blood vessels, which supports the possibility of the tumor cells being pushed out of the bladder into the blood stream during this procedure. These factors, together with the complexity of removing the entire tumor that invades the bladder wall, might lead to an increased risk of developing metastases. Previous small-scale research has suggested that the level of circulating tumor cells (CTCs) in the blood may increase after TURBT which may result in the formation of micrometastases and as a consequence early disease recurrence. Furthermore, meta-analysis results showed that MIBC patients with CTCs had a worse prognosis compared to patients with no CTCs.

Study objective

To validate the suggestion that transurethral resection of bladder tumors in patients with suspected muscle invasive bladder cancer can lead to circulating tumor cells.

Study design

Patients who are cystoscopically suspected for muscle invasive bladder cancer will be asked to consent with a blood draw just prior and just after the TURBT. The blood samples are transported at room temperature within 24 hours to the Radboudumc, processed, and tumor cells are counted with the Parsortix system.

Study burden and risks

Negligible

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Noord 21
Nijmegen 6525 EZ
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Noord 21
Nijmegen 6525 EZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients suspected of muscle invasive bladder cancer, planned for transurethral resection for local staging

Exclusion criteria

Not capable of giving informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2021
Enrollment:	25

Type:	Actual

Ethics review

Approved WMO Date:	17-06-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL76997.091.21