

Multi-parametric MRI in patients suspected for muscle invasive bladder cancer: a new local staging paradigm

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON53371

Source

ToetsingOnline

Brief title

BladParadigm

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym

Bladder cancer

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Bladder cancer, Clinical trial, multiparametric MRI, transurethral resection of the bladder tumor

Outcome measures

Primary outcome

progression free survival at 2 years after diagnosis

Secondary outcome

time to definitive treatment, quality of life, healthcare costs and cost-effectiveness

Study description

Background summary

Muscle invasive bladder cancer (MIBC) is one of the very few types of cancer for which the prognosis has not improved for decades. About 50% of the 2000 patients per year in the Netherlands will die from the disease within 5 years despite curative local treatment. This suggests that in many patients the disease has already metastasized at the time of diagnosis, even though imaging shows no metastasis. We hypothesise that the standard local staging method, the transurethral resection of the bladder tumour (TURBT), is partly responsible for tumour cell spread, because this procedure cuts through the tumour.

Study objective

The aim of this study is to determine whether multiparametric MRI (mpMRI) of the bladder, in combination with an outpatient biopsy for histological confirmation, is a faster, safer, cheaper and therefore more cost-effective way to detect or eliminate muscle invasion in bladder cancer.

Study design

Two-arm multicenter randomised controlled trial

Intervention

mpMRI of the bladder with outpatient biopsy of the tumour

Study burden and risks

The burden and risks to participate in BladParadigm are limited. No extra hospital visits are required, filling in the questionnaires takes 5 minutes maximum per questionnaire, with a maximum of 4 questionnaires in total

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients (18+ years of age) with clinically suspected MIBC, without lymph node or distant metastases, written informed consent

Exclusion criteria

Unable or unwilling to undergo mpMRI; Unfit for TURBT; Unfit for definitive treatment with curative intent; A history of cancer, including bladder cancer, except non-melanoma skin cancer or prostate cancer on active surveillance

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	06-12-2023
Enrollment:	360
Type:	Actual

Medical products/devices used

Generic name:	multiparametric magnetic resonance imaging
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	18-07-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO	
Date:	17-10-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	29-01-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	10-10-2024
Application type:	Amendment
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
ClinicalTrials.gov	NCT05779631
CCMO	NL83685.091.23