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

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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…

Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON53371

Source
ToetsingOnline

Brief title
BladParadigm

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
Bladder cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw

Intervention

- Medical device

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

Explanation

N.a.

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

Trial sites in the Netherlands

Ziekenhuisgroep Twente
Target size: 22

Bernhoven
Target size: 15

OLVG
Target size: 15

Amsterdam UMC
Target size: 30

St. Antonius Ziekenhuis

Target size: 20

Maasziekenhuis
Target size: 20

Jeroen Bosch Ziekenhuis
Target size: 20

Medisch Spectrum Twente (MST)
Target size: 15

Meander Medisch Centrum
Target size: 15

Radboud Universitair Medisch Centrum
Target size: 24

Universitair Medisch Centrum Utrecht
Target size: 15

VieCuri Medisch Centrum
Target size: 20

Rijnstate
Target size: 20

Treant
Target size: 15

Erasmus MC, Universitair Medisch Centrum Rotterdam
Target size: 10

Antoni van Leeuwenhoek (AVL)
Target size: 24

Canisius Wilhelmina Ziekenhuis
Target size: 30

Ziekenhuisvoorzieningen Gelderse Vallei
Target size: 30

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, or history of a solid tumor but disease-free ≥5 years since last treatment

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Other type of control
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	06-12-2023
Enrollment:	360
Duration:	24 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	multiparametric MRI

Registration:	Yes - CE intended use

IPD sharing statement

Plan to share IPD: Yes

Plan description
Participants sign to agree to share the data (anonymously), only after approval from the ethics committee. All data (patient data, QoL data and imaging data) can be shared (anonymous). Data will be published in DANS Data Stations or Radboud Data Respository without restrictions, after an embargo period of 12 months to enable publication of new results based on the data. The CC BY license applies.

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)
Approved WMO Date:	13-03-2025
Application type:	Amendment
Review commission:	METC Oost-Nederland

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
Research portal	NL-007019