

Improvement of Prostate Cancer Diagnosis: a Multi-center, Observational Evaluation of Pre-biopsy MRI-pathways

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22158

Source

NTR

Brief title

IMPROVE MRI

Health condition

Prostate cancer

Sponsors and support

Primary sponsor: N/a

Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The follow-up of men in different mpMRI-‘first’ pathways with regard to detection rates of indolent- and csPCa and prostate biopsy rates during a follow-up period of three years.

Secondary outcome

- For different biopsy strategies, the accuracy of the Gleason score (GS) of (MRDB) biopsies in predicting the definite GS at whole mount radical prostatectomy specimens.
- A cost-effectiveness assessment to analyze the different biopsy strategies.
- The histopathological results of biopsies in relation to mpMRI assessment.
- The value of the (MRI-based) risk calculator (e.g. ERSPC-RC3).
- The role of multidisciplinary team meetings in clinical shared-decision making.
- How to manage equivocal (PI-RADS 3) lesions.
- A comparison of targeted biopsy methods (MR-in bore, MR-TRUS fusion and MR-cognitive biopsies) and the additional value of systematic biopsy.

Study description

Background summary

Prostate cancer (PCa) is one of the most commonly diagnosed malignancy in men. The limited diagnostic accuracy of systematic transrectal ultrasound guided biopsies (TRUSGB) raised an emerging interest in the diagnostic value of multiparametric magnetic resonance imaging (mpMRI). Recent studies have shown the superiority and feasibility of an mpMRI-‘first’ pathway with upfront mp-MRI in biopsy-naïve men suspected with prostate cancer. This diagnostic approach can accurately detect clinically significant prostate cancer (csPCa) while minimizing the amount biopsies and over-detection of indolent PCa, by only performing a prostate biopsy in case of suspicious mpMRI. However, this is at the risk of under-detecting csPCa. Negative predictive values are reported to be high, but mid-long-term outcomes in clinical practice have not yet been described. Furthermore, the diagnostic follow-up of men in case of high suspicion for csPCa at mpMRI with benign biopsy results is still unclear. This multi-center observational study will investigate mpMRI-‘first’ diagnostic pathways in biopsy-naïve men with suspected prostate cancer, including follow-up.

Study objective

Men without a suspicious prostate MRI (i.e. PI-RADS 1-2) can safely avoid (systematic) biopsy.

Study design

Time of inclusion: 24 months

Time of follow-up: 36 months (interim analysis after 12 and 24 months).

Contacts

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Eligibility criteria

Inclusion criteria

- Biopsy-naïve men, aged 18-80 years.
- Clinical suspicion of prostate cancer (i.e. PSA $\geq$ 3.0 ng/ml and/or abnormal DRE).
- Men must be able to comprehend and sign an informed consent and must be able to comprehend and sign an MRI screening form (to search for metal device/foreign bodies/claustrophobia).

Exclusion criteria

- History of previous prostate biopsy.
- Already proven prostate cancer or history of PCa.
- Contraindications for an MRI scan (with gadolinium contrast).
- History of invasive treatments for BPH or lower urinary tract symptoms (LUTS), e.g. transurethral resection of the prostate; heat, laser or ultrasound treatments in the last 12 months.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 01-03-2019
Enrollment: 700
Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 24-01-2020
Application type: First submission

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
NTR-new	NL8331
Other	METC Radboudumc : CMO 2019-5191

Study results