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

Gepubliceerd: 24-01-2020 Laatst bijgewerkt: 07-12-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22158

Bron
Nationaal Trial Register

Verkorte titel
IMPROVE MRI

Aandoening

Prostate cancer

Ondersteuning

Primaire sponsor: N/a
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Contactpersonen

Publiek

Radboudumc
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Biopsy-naïve men, aged 18-80 years.
- Clinical suspicion of prostate cancer (i.e. PSA ≥ 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2019
Aantal proefpersonen:	700
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8331
Ander register	METC Radboudumc : CMO 2019-5191

Resultaten