Sequential imaging for suspicion of Prostate cancer Reducing Overdiagnosis and Unnecessary biopsy with Timely diagnosis of significant cancer

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Ethical review	Approved WMO
Status	Pending
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON57300

Source
ToetsingOnline

Brief title
SPROUT

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Stichting Onderzoek en Innovatie van de maatschap Urologen voor U

Intervention

Keyword: biopsy, MRI, overdiagnosis, prostate cancer

Outcome measures

Primary outcome

Safety endpoint (non-inferiority): Detection percentage of ISUP GG >=2 PCa during 48 months of follow up compared with the percentage of total ISUP GG >=2 PCa detected during the study, including findings from end-of-study biopsies.

Effectiveness endpoints: Detection of ISUP GG =1 and negative biopsy rates during 48 months of follow up compared to total ISUP GG =1 and negative biopsy rates including those obtained from end-of-study biopsy; prostate biopsy rates during the study compared to total number of prostate biopsies including end-of-study biopsies.

Secondary outcome

Cost-effectiveness: MRI-, complication-, outpatient consultation- and treatment rates.

Health-related quality of life evaluated by questionnaires (EPIC-26 en 6-item short STAI).

Upgrading and downgrading rates of MRI lesions.

Study description

Background summary

Suspicion for prostate cancer (PCa) based on elevated PSA level is a common

reason for urologic referrals. State-of-the-art diagnostic algorithms apply risk calculator and/or MRI to indicate prostate biopsy. However, overdiagnosis remains a significant shortcoming of the current pathway, especially in men with an intermediate risk of harboring significant PCa (PIRADS 3 and PIRADS 4 with PSA density < 0.15) In these groups, a prostate biopsy results in a negative result or insignificant prostate cancer (ISUP GG 1) in about 70% of cases.

Study objective

The primary objectives of this study are to evaluate the safety and effectiveness of a novel diagnostic approach applying PSA-density and MRI-imaging-based monitoring, as opposed to immediate prostate biopsy, in men with an intermediate risk of harbouring clinical significant PCa, with timely detection of previously undetected tumours. This approach aims to preserve the detection of ISUP GG >=2 PCa, while reducing overdiagnosis of ISUP GG = 1 PCa, and avoiding unnecessary biopsies.

Study design

prospective Dutch multicenter study

Intervention

Biannual PSA test and annual MRI prostate. After 48 months end-of-study biopsies in case there is still a visible lesion on MRI.

Study burden and risks

Every six months PSA measurements will be performed and with annual prostate MRI. This is similar to follow-up in regular care for many men who would receive direct biopsy according to standard of care (follow-up after negative biopsy, or follow-up during active surveillance for low risk PCa). Two large RCTs (PIVOT/PROTECT) showed that monitoring of men diagnosed with (cs)PCa was not related to a higher (PCa-related) mortality, thus a negative impact on oncological outcomes is highly unlikely. An end-of-study biopsy is conducted in all men who were not subjected to one during the study with still a visible lesion (PIRADS >= 3), to identify any (potential) cases of PCa that may have been missed, to validate the follow-up protocol.

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

- Men aged > 18 years old
- Life expectancy > 10 years
- iPSA < 20 ng/ml
- no signs of extracapsular disease by digital rectal examination
- Mentally competent and understanding of benefits and potential burden of the study.
- Written and signed informed consent.
- Intermediate-risk category for suspicion of prostate cancer determined by bpMRI results and PSA density (PSAd): PIRADS 3 or PIRADS 4 with PSAd <=0.15.
- Willing to undergo follow-up protocol (PSA every 6 months, MRI every 12 months, for four years; end of study biopsy in case of PIRADS >= 3 lesion)

Exclusion criteria

- Men who have previously undergone a prostate biopsy
- Men who have a prior PCa diagnosis
- Not fulfilling inclusion criteria

- Using any (anti-)hormonal therapy, including 5-alpha reductase inhibitors
- Identified germline mutation associated with an increased risk of prostate cancer (e.g., in BRCA1 or BRCA2 genes
- Secondary malignancy, besides basal cell carcinoma of the skin, for which the patient is receiving active treatment at the time of inclusion
- Severe claustrophobia or other conditions that make MRI unsuitable (e.g., metal implants, pacemakers, or other metal-containing devices in the body)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2025
Enrollment:	503
Type:	Anticipated

Ethics review

Approved WMO

Date:	17-02-2025
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL87954.100.24