Prostate cancer Research International: Active Surveillance (PRIAS) MRI study

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To study the value of mpMRI with subsequent targeted biopsies after inclusion to more accurately grade prostate cancers of men on active surveillance. Furthermore, the value of mpMRI in reducing the number and amount of biopsies will be studied.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON50734

Source
ToetsingOnline

Brief title
PRIAS + MRI

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Prostatic disorders (excl infections and inflammations)

Synonym
Prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Active Surveillance, MRI, PRIAS, Prostate Cancer

Outcome measures

Primary outcome

The main endpoint is the percentage of men upgraded (Gleason score >=7) at

inclusion and at repeat biopsies.

Secondary outcome

Secondary endpoints are the therapy free survival rate, number of biopsies

performed, biopsy complications, results after deferred radical treatment,

development of metastasis and prostate cancer specific mortality.

Study description

Background summary

Prostate cancer often has an indolent growth pattern. Radical treatment of these cancers therefore results in unnecessary side-effects and deterioration of quality of life. Active surveillance aims at postponing or even avoiding this radical treatment, without affecting oncological outcome.

The at the Erasmus MC initiated study *Active surveillance: Een afwachtend beleid met de mogelijkheid tot uitgestelde curatieve behandeling bij mannen met prostaatkanker; richtlijn en studie in de regio Rotterdam (PRIAS)* is currently the largest active surveillance study worldwide. Although short term results are promising, the selection of men with truly *indolent* prostate cancer could be improved. Furthermore the criteria to switch to radical treatment are not optimal, with some men being treated unnecessary and for some men treatment is deferred to long.

MpMRI of the prostate with subsequent targeted biopsies could improve Gleason grading of the prostate cancer and therefore improve upfront selection and follow-up of men on active surveillance, further reducing the number of men with intermediate risk instead of low risk cancers selected initially for active surveillance . If mpMRI with targeted biopsies improves Gleason grading, surrogate measures of Gleason progression currently used in the PRIAS study

(more than 2 cores positive, PSA-DT <3 year) could be improved and replaced.

This side study of the PRIAS study aims at investigating the value of mpMRI at inclusion and during follow-up of men on active surveillance.

Study objective

To study the value of mpMRI with subsequent targeted biopsies after inclusion to more accurately grade prostate cancers of men on active surveillance. Furthermore, the value of mpMRI in reducing the number and amount of biopsies will be studied.

Study design

This side study of the PRIAS study is a prospective cohort study. Comparisons will be made with historically matched PRIAS participants.

Study burden and risks

The additional burden consist of a maximum of 7 mpMRIs during 7 years of follow-up and a maximum of 6 additional biopsies per repeat biopsy visit. Risk of MRI include allergy to contrast media. This risk is reduced as much as possible by excluding participants with a known contrast allergy. Studies have shown that taking additional biopsies during a biopsy procedure does not increase the risk of complications, except the pain that can be associated with the extra biopsies taken. On the other hand mpMRI could reduce the amount of repeat biopsy visits for some men with low PSA-DT. Furthermore it could improve the Gleason grading of the prostate cancer at inclusion, therefore better selecting men with true *indolent* prostate cancer, and at follow-up reducing the amount of unnecessary radical treatments.

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

1) Included into the PRIAS study <7 years ago
2) Men should be fit for curative treatment
3) Participants must be willing to attend the follow-up visits
4) Participants must be willing and able to attend follow-up MRIs and targeted biopsies

Exclusion criteria

1) Men who cannot or do not want to be irradiated or operated
2) A former therapy for prostate cancer
3) Men with a contraindication for MR

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-03-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	23-10-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-10-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL45884.078.13