PRostate Evaluation for Clinically Important disease: Sampling using Image-guidance Or Not?

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The main purpose of this study is to assess whether MRI-targeted biopsy can detect a similar amount of cancer as 10-12-core TRUS biopsy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42747

Source
ToetsingOnline

Brief title
PRECISION

Condition

- Other condition

Synonym
prostatecancer

Health condition

Prostaatkanker detectie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biopsy, Guided, MRI, TRUS

Outcome measures

Primary outcome

Proportion of men with clinically significant cancer detected

Secondary outcome

Proportion of men in MRI arm who avoid biopsy

Proportion of men in whom MRI score for suspicion of clinically significant

cancer was 3, 4 or 5 but no clinically significant cancer was detected

Proportion of men who go on to definitive local treatment (e.g. radical

prostatectomy, radiotherapy, brachytherapy) or systemic treatment (e.g. hormone

therapy, chemotherapy)

Proportion Gleason grade upgrading in men undergoing radical prostatectomy

Post-biopsy complications

Health-realted quality of life

Study description

Background summary

The standard way of diagnosing prostate cancer is to carry out a trans-rectal ultrasound guided (TRUS) biopsy. This involves inserting an ultrasound probe into the back passage after which 10-12 pieces of tissue are taken from the

prostate from areas in the prostate most likely to contain cancer. Another way of doing a biopsy is to perform an MRI scan of the prostate on an earlier day and use that information to help take the biopsies. If there is a suspicious area in the prostate on the MRI, a few biopsies can be directed at where the suspicious area is thought to be, also using a probe in the back passage. Up to 12 pieces of tissue can be taken. If there is no suspicious area on the MRI, which occurs in about 30% of men, then no biopsy will be taken at all.

We currently do not know for certain whether using MRI directed biopsies will allow us to detect the same, more or less prostate cancer than if we do not use MRI. Current evidence supports the idea that using MRI directed biopsies may detect a similar amount of cancer to when it is not used but one advantage is it may allow a man to avoid a biopsy.

Study objective

The main purpose of this study is to assess whether MRI-targeted biopsy can detect a similar amount of cancer as 10-12-core TRUS biopsy.

Study design

randomised study

Intervention

MRI-guided biopsy

Study burden and risks

Patiënt are required to fill out 3 questionnaires. Also, there is a chance that MR-targeted biopsy does not detect as many cancer as 10-12 core systematic TRUS biopsy. So these patiënt will not be treated while they should be treated. However, current evidence supports the idea that using MRI directed biopsies may detect a similar amount of cancer to when it is not used but one advantage is it may allow a man to avoid a biopsy.

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 at least 18 years of age regerred with clinical suspicion of prostate cancer who have been advised to have a prostate biopsy.
PSA * 20ng/ml within the previous 3 months
Suspected stage * T2 on rectal examination (organ-confined prostate cancer) within the previous 3 months

Exclusion criteria

Prior prostate biopsy
Prior treatment for prostate cancer
Contrainidaction to MRI
Contraindication to prostate biopsy
evidence of untreated urinary tract infection
Previous hipreplacement surgery, metallic hip replacement

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-12-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	30-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-04-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-07-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT02380027
CCMO	NL54630.091.15

Study results

Date completed: 21-09-2017

Actual enrolment: 17

Summary results
Trial is onging in other countries