Real-time lesion targeting during MR-guided prostate biopsy using an iPad: a pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON42502

Source
ToetsingOnline

Brief title
Real-time lesion targeting during MR-guided prostate biopsy

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
malignant prostate tissue, prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Radiologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biopsy, iPad, MRI, Prostate

Outcome measures

Primary outcome

To establish the clinical feasibility in patients of real-time lesion targeting

during MR-guided prostate biopsy using an iPad.

Secondary outcome

To evaluate the time to first biopsy and total procedure time of MR-guided

prostate biopsy with and without real-time lesion targeting.

Study description

Background summary

Prostate cancer (PCa) is the most diagnosed non-skin cancer in men in the Netherlands. Population aging and wider spread use of prostate-specific antigen (PSA) screening tests are expected to further increase diagnosis of this disease. In case of an elevated PSA, systematic transrectal ultrasound (TRUS)-guided prostate biopsy is currently the standard technique to detect PCa. However, as PSA is a non-specific marker for prostate cancer, urologists are increasingly confronted with the dilemma of seeing patients with a high clinical suspicion of PCa but negative initial TRUS-guided biopsy results. More recently, the use of multi-parametric MR imaging has been well established in detecting PCa, showing high localization accuracy. Consequently, MR imaging has also been proposed in guiding biopsies towards cancer suspicious regions, with the aim of improving diagnostic performance. MR-guided prostate biopsy is routinely used in clinical practice at this institution. Nevertheless, an important limitation of this procedure are long procedure times, mainly due to the time-consuming process of lesion targeting. We devised a method for real-time lesion targeting during MR-guided prostate biopsy using an iPad inside the MR-room.

Study objective

The purpose of our study is to prospectively establish in vivo in patients proof of principle for real-time lesion targeting during MR-guided prostate

biopsy using an iPad inside the MR-room. Additionally, we will evaluate the time to first biopsy and total procedure time of MR-guided prostate biopsy with and without real-time lesion targeting against a matched patient cohort.

Study design

Prospective, non-randomized, single centre pilot study

Intervention

All subjects will undergo MR-guided prostate biopsy with real-time lesion targeting

Study burden and risks

Patients will undergo MR-guided prostate biopsy in a single session, as is routine clinical practice, placing no increased burden on the patients. Most important potential risk of the study would be unwanted attraction of the iPad to the MR scanner, causing injury to the patient or operator. In-house safety tests have been performed to determine safe limits in which the iPad can be used inside the MR-room. This will be safeguarded by marker indications placed inside the MR-room and mounting of the iPad to an MR-compatible IV pole to make sure it is secured at all times. Also, the MR-compatible IV-pole will be securely attached to the wall or MRI scanner table to prevent it from falling. Furthermore, we will have an additional researcher be present during all biopsy procedures who is charged with ensuring and safeguarding the safe working environment within the MR scan room. With these safety measures, no additional risk to the patient or operator is expected. Also, no increased risk is expected with regards to diagnostic performance of the biopsy procedure as a standard confirmation scan according to the current standard clinical protocol will be obtained before each actual biopsy is taken and, if required, the needle guide is adjusted to ensure accurate sampling of the target region. Most important potential benefit for patients could be faster procedure time, reducing the time the patient has to lie inside the MR scanner and, thereby, patient discomfort.

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

- 21 years of age or more
- PSA >4.0 ng/mL and/or positive digital rectal examination
- Single suspicious lesion (PIRADS 4 or 5) on diagnostic MR imaging examination
- Signed MRI screening form (to search for metal device/foreign bodies/claustrophobia)
- Signed IRB-approved informed consent form

Exclusion criteria

- Patients unable to undergo MR imaging, including those with contra-indications
- Contra-indications to MR-guided prostate biopsy
- Metallic hip implant or any other metallic implant or device that distorts local magnetic field and compromises the MR imaging quality
- Multiple suspicious lesions on diagnostic MR imaging examination
- Impossibility to obtain a valid informed consent

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-06-2016
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	iPad (tablet) in combination with IFE planning-software
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	05-11-2015
Application type:	First submission
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
CCMO	NL53597.091.15

Study results

Date completed:	03-10-2016
Actual enrolment:	20