MR robot guided prostate biopsy: 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-OMON32539

Source
ToetsingOnline

Brief title
Robot guided prostate biopsy

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
malignant prostate tissue, Prostaat cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biopsy, MR imaging, Prostate cancer, Robot guided intervention

Outcome measures

Primary outcome

To establish the feasibility of MR robot guided prostatic needle intervention

in patients.

Secondary outcome

to determine the accuracy of the robotic needle-guide positioning with MR

imaging guidance within a standard closed-bore MR imager.

Study description

Background summary

In 2005, prostaatcancer was with 8.800 new cases the most common form of cancer in men in the Netherlands. Today, in regular clinical practice prostate biopsies are performed under transrectal ultrasound (TRUS) guidance. Even though the traditional ultrasound appearance of prostate cancer is a hypoechoic lesion, other conditions such as prostatitis and prostatic intraepithelial neoplasia may also present as hypoechoic lesions. Initial detection of prostate cancer rates for extended schemes range between 22% and 44%.
Image guided biopsies towards tumor suspicious regions have been advocated to improve tumor detection. MR imaging, with its higher tumor detection ability, has been used to direct biopsies both under TRUS and MR guidance. Experience of using MR guided biopsy devices at 1.5T, to biopsy tumor suspicious regions on anatomical T2-weighted MR images, has been previously published. Robotics is a new field in medicine due to stringent safety criteria. Robots are most often used in minimally invasive procedures, such as cardiac, bladder, prostate, and neurosurgery.
Robotic assistance for MR-guided interventions with the prostate has been investigated at several institutions. Most robots have a manual positioning system, which means that the patient has to be removed from the scanner in order to correct the position. The department of Radiology of the Radboud University Nijmegen Medical Centre (RUNMC) has conceptualized, tested (bench), and manufactured a fully MR imaging- compatible robotic system designed to perform MR imaging-guided transrectal needle intervention of the prostate. This

MR-compatible robotic device uses a pneumatic mechanism, which can be controlled next to the MR console.

Study objective

The purpose of our study is to prospectively establish in vivo in patients proof of principle for the RUNMC MR imaging-compatible robotic system designed for image-guided prostatic needle intervention.

Study design

Prospective, non-randomized, single centre pilot study. Twenty patients will be included in this pilot study.

Intervention

The robotic system consists of the robot and its controller unit. The controller unit includes a computer, motion control elements, a series of electropneumatic interfaces, and a software package. It is located outside the MR imaging room and is connected to the robot by plastic hoses, which are 10 m in length and carry air wires. The robot itself fits into a standard closed-bore MR imager, and it is designed to interact with the patient within the imager. To achieve full MR imaging compatibility, the entire robot is built of nonmagnetic and dielectric materials, such as plastics and rubber. Furthermore, a pneumatic actuator was specifically developed for this application. The pneumatic motor achieves high precision in a safe and easily controllable manner. Pressure waves are used to set the motors in motion. These waves are created by a pneumatic distributor remotely located in the controller unit and are transmitted to the robot through the plastic hoses. The motors use solely pressured air but no electricity whatsoever. These features prevent the robot from creating any interference with the electromagnetic environment inherent to MR imaging technology. To meet standard safety requirements for the use in medical applications, the robot's motors are designed for fail-safe operation. Any form of malfunction leads to a lock and cannot result in uncontrolled motion. The motors provide the robot with six degrees of freedom to place and orient an end effector as desired. The end effector is easily detachable from the robot and could be replaced with other end effectors (for other percutaneous interventions) in the future. The needle guide is connected to the robotic arm.

Study burden and risks

The device poses no risk for the patient. During manipulation of the biopsy robot the mechanical construction will prevent any possible harm for the patient. The pneumatic motor allows for easily controllable motion with fail-safe operation. Furthermore, the needle guide has a fail-safe mechanism as

well. The biopsy itself will be performed by an experienced radiologist.

MR imaging may cause some discomfort, such as feelings of claustrophobia due to loud sounds of the MR instrument during the study. Patients are screened for prior claustrophobic symptoms using the same screening form described above to search for metal device and foreign bodies. Earplugs are provided to all patients in order to minimize the discomfort related to the loud noise.
When the biopsy is performed without anesthesia, 65% to 90% of men report mild to severe pain. Patients receiving lidocaine anesthesia report a mean pain score of 1.6 to 2.4 (0 to 10, 0 = no pain and 10 = worst pain). A topical anesthetic gel will be applied as lubricant at the time of the prostate biopsy.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
6500HB Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
6500HB Nijmegen
Nederland

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
- Suspicious lesion on diagnostic MR imaging examination
- Signed IRB-approved informed consent form

Exclusion criteria

- Patients unable to undergo MR imaging, including those with contra-indications
- Contra-indications to MR robot guided prostate biopsy

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):	01-12-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Biopsy needle
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-02-2009
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	NL25252.091.08