Clinical Feasibility Study of Prototype 1.5T & 3T Endorectal Coils

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To obtain data, images and feedback from the initial clinical use of investigational four channel output eCoils designed for Siemens 1.5T and 3.0T scanners compared to the current, commercially available single channel eCoils for these field...

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

Summary

ID

NL-OMON34331

Source
ToetsingOnline

Brief title
Endorectal coil MRI

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
prostate 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: endorectal coil, MR, prostate

Outcome measures

Primary outcome

Investigational 1.5T and 3.0T Siemens eCoils, tuning devices and the appropriate configuration files to enable use of the coil will be provided for the purpose of this study. Patients will be positioned on the scanner table and the eCoil inserted by an experienced radiologist. All coils will be filled with perfluorocarbon. Patients will then be scanned utilizing the imaging protocol, (pulse sequences noted above) as are normally employed by the radiology department of the RUNMC when performing endorectal prostate MR studies on their patients. Images obtained with the investigational four channel output eCoil in conjunction with or without a surface coil and images obtained using commercial 1.5T endorectal probes with any fluids other than air are NOT to be used for diagnostic purposes.

Secondary outcome

N/A

Study description

Background summary

Prostate cancer is the most frequent non-cutaneous malignancy in the western male population, with almost 200,000 newly diagnosed patients in the United States in 2008 [1]. Due to widespread use of the prostate-specific antigen (PSA) test and the lowered PSA threshold for biopsy, the number of newly diagnosed Pca*s strongly increased [2]. Treatment selection depends on patient age and general health, cancer stage and grade, morbidity and treatment

mortality, together with the preference of the patient and physician. Current opinion is that localized prostate cancer can be treated successfully by radical retropubic prostatectomy in the patient group with a life expectancy of 10 to 15 years or more.
Clinical assessment by digital rectal examination and measurement of prostate specific antigen (PSA) level is not accurate in determining local stage, with underestimations in as many as 40-60% of cases [3]. Accurate staging with additional imaging methods is therefore an important issue for correct management of prostate cancer patients. Among these imaging techniques, transrectal ultrasound (TRUS) may enable correct assessment of locally advanced tumors but is not sensitive enough to detect initial extraprostatic extension across the capsule or into the seminal vesicles in clinically confined lesions [4, 5].
Magnetic resonance (MR) imaging is considered to play an important role in local staging of prostate cancer. Initially MR imaging was performed using a conventional body coil with limited anatomical resolution. With the introduction of new MR sequences, new coils and other technical developments numerous studies have attempted to improve local staging. The diagnostic capability of MR imaging in preoperative staging of prostate cancer is currently being established.
The use of endorectal coils (eCoils) offers new possibilities in prostate cancer imaging. Endorectal coils increase the signal-to-noise ratio compared to pelvic phased array coils, which may lead to a higher spatial resolution and subsequently better staging performance. The clinical available endorectal coil is used over 15 years in our clinical practice (Radiology Department of Radboud University Nijmegen Medical Centre). Recently, a new prototype endorectal coil was developed with four receive channels compared to 1 receive channel in the current available endorectal coil. This new endorectal coil allows for parallel imaging techniques which subsequently can lead to decreased imaging time with similar image quality (compared to the clinical available coil) or increased image quality with similar acquisition time.

Study objective

To obtain data, images and feedback from the initial clinical use of investigational four channel output eCoils designed for Siemens 1.5T and 3.0T scanners compared to the current, commercially available single channel eCoils for these field strengths and this MRI scanner.

Study design

This will be a prospective non-randomized single center study (RUNMC). A total of 8 patients will be recruited and imaged with the current, commercially available eCoil and the investigational four channel output eCoil at 1.5T and 3T (Four patients` will be imaged with the current commercially available eCoil

and the investigational eCoil at 1.5T and four patients will be imaged with the current commercially available eCoil and the investigational eCoil at 3.0T. Therefore each patient will have an additional endorectal MR examination (with the prototype) direct after the diagnostic clinical endorectal MR examination.

Study burden and risks

MR imaging may cause some discomfort, such as feelings of claustrophobia and discomfort 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. The insertion of the endorectal coil may cause discomfort. Lidocaine gel is inserted into the rectum for local anesthesia of the rectal wall.

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

• Newly diagnosed and biopsy proven prostate cancer
• No previous treatment for prostate cancer
• Signed informed consent by patient
• 18 years of age or more
• Signed screening form (to search for metal device/foreign bodies/claustrophobia)
• No contraindications for and are eligible to have a MR scan of their prostate utilizing an endorectal coil

Exclusion criteria

• Impossibility to obtain a valid informed consent
• Patients unable to undergo MR imaging, including those with contra-indications
• Metallic hip implant or any other metallic implant or device that distorts local magnetic field and compromises the quality of MR imaging

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2011
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	endorectal coil
Registration:	No

Ethics review

Approved WMO Date:	11-07-2011
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	NL33514.091.10