MR-guided focal cryosurgery of the prostate: a pilot study*

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Main objective of this study is to test the safety and feasibility of MR-guided focal cryosurgery in newly diagnosed prostate cancer patients and in patients with recurrent prostate cancer after radiotherapy. Secondary objectives are: to determine...

Ethical review	Not approved
Status	Will not start
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON34160

Source
ToetsingOnline

Brief title
MR-guided focal cryosurgery

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)
- Male genital tract therapeutic procedures

Synonym
Prostate cancer, Prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Patientenzorg

Intervention

Keyword: cryosurgery, focal therapy, interventional MRI, prostate cancer

Outcome measures

Primary outcome

The safety and feasibility of MR-guided focal cryosurgery in vivo in newly diagnosed prostate cancer patients and in patients with recurrent prostate cancer after radiotherapy is described by potential complications and ASTRO-criteria for disease-free survival.

Secondary outcome

The accuracy of cryoneedle placement under MR guidance is given by measuring the in plane error at the MR images retrospectively. The accuracy of MR temperature mapping by measuring the temperature with MR compatible temperature sensors. The correlation between the MR results from multimodality MR and temperature mapping with the pathological results.

Study description

Background summary

Prostate cancer is the most frequent malignancy in the male population of developed countries and has a substantial socio-economic impact.
This project has the goal to develop and test the feasibility of a novel focal treatment for these patients, namely MR-guided cryoablation. The project combines three novel approaches implemented at our institution for the prostate: functional MR imaging techniques to identify the tumor recurrence, MR robot-guided placement of probes, and temperature mapping of the prostate during thermal ablation.
Two patient cohorts will be included in this feasibility study: 10 patients with unilateral prostate cancer scheduled for radical prostatectomy (group A) and 20 patients with biopsy-proven local recurrence (group B). Potential complications will be recorded and ASTRO criteria for disease-free survival

will be used to assess the success rate.
The suggested technique holds the promise to provide a faster, less expensive and less invasive alternative to salvage prostatectomy or radiotherapy with also less side effects.

Study objective

Main objective of this study is to test the safety and feasibility of MR-guided focal cryosurgery in newly diagnosed prostate cancer patients and in patients with recurrent prostate cancer after radiotherapy. Secondary objectives are: to determine the accuracy of cryoneedle placement under MR guidance, to assess the accuracy of MR temperature mapping and to correlate the MR imaging results from multimodality MR and temperature mapping with the whole mount section histopathology.

Study design

A prospective, non randomized, multicentre pilot study. This trial will be run at the UMC St Radboud, where patients will be included in the UMC st Radboud and Canisius Wilhelmina Ziekenhuis from September 2010 to September 2012.

Intervention

Patient group A will undergo additional MR-guided focal cryosurgery before they undergo radical prostatectomy and patient group B will receive MR-guided cryosurgery instead of US-guided cryosurgery.

Study burden and risks

Potential patient risks in this study as mentioned by complications of cryosurgery, or serious unexpected events and patient burden in form of time investment and possible discomfort of MR examinations and cryosurgery are outweighed by potential benefits for patients. Patients will possibly benefit from a more accurate needle placement and consequent cryosurgery through MR guidance and consequently their individual risk stratification will be optimalized.

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

We plan to enroll thirty patients in total, divided over two groups; A and B. Ten patients with newly diagnosed and pathological proven PCa, which have a tumor confined to one prostate lobe and which is not located near the neurovascular bundle and no prior hormonal or radiation treatment will be included in group A. In group B twenty patients with biopsy-proven local recurrence of the prostate without distant metastases after radiotherapy will be included.;Additional inclusion criteria counting for both groups:
• 18 years of age or more
• Pathologically proven PCa
• Signed screening form (to search for metal device/foreign bodies/claustrophobia)
• Signed IRB-approved informed consent form

Exclusion criteria

• Impossibility to obtain a valid informed consent
• Patients unable to undergo MR imaging, including those with contra-indications
• Contra-indications to MR guided cryosurgery (colitis ulcerosa, rectal pathology or dominoperineal resection)
• Metallic hip implant or any other metallic implant or device that distorts local magnetic field and compromises the quality of MR imaging

• A prostate volume > 50 mL
• No data available from whole-mount step-section pathologic analysis to use as reference standard (group A)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	SeedNet MRI System
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	19-10-2010
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	NL32429.091.10