MR-guided focal laser ablation of the prostate: a pilot study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON36226

Source
ToetsingOnline

Brief title
MR-guided focal laser ablation

Condition

- Miscellaneous and site unspecified neoplasms benign
- Prostatic disorders (excl infections and inflammations)

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: focal therapy, laser ablation, MR-guided intervention, prostate cancer

Outcome measures

Primary outcome

The feasibility of MR-guided focal laser ablation in vivo in newly diagnosed PCa patients. Potential complications are recorded, and the success rate will be determined by MR-imaging after 1 - 3 weeks and a combination of MR imaging and MR-guided biopsy after 6, 12, 18, 24 and 36 months.

Secondary outcome

• To determine the accuracy of laser fibre placement under MR guidance by measuring the 3D error at the MR images retrospectively.

• To correlate the MR results from multimodality MR and temperature mapping with the pathological results.

• To determine the role of imaging in predicting histological outcomes of transrectal focal laser ablation therapy in the treatment of localised prostate cancer.

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 laser-induced interstitial thermal therapy (LITT) or focal laser ablation. The project combines three novel approaches implemented at our institution for the prostate: functional MR imaging techniques to identify the tumor, MR-guided placement of laser fibers, and temperature mapping of the prostate during thermal ablation.

Two patient cohorts will be included in this feasibility study: 10 patients with low-risk prostate cancer scheduled for radical prostatectomy, who will get the laser ablation as extra treatment (group A) and 20 patients with low-risk prostate cancer, who will get the focal therapy as main treatment (group B). Potential complications will be recorded and the success rate will be determined by MR-imaging after 1 - 3 weeks and a combination of MR imaging and MR-guided biopsy after 6, 12, 18, 24 and 36 months.The suggested technique holds the promise to provide a faster, less expensive and less invasive alternative to radical prostatectomy with also less side effects.

Study objective

Main objective of this study is to test the feasibility and to determine the short and medium term histological cancer control of focal therapy using MR-guided focal laser ablation therapy in the treatment of localised prostate cancer. Secondary objectives are: to determine the accuracy of laser fibre placement under MR guidance, to correlate the MR results from multimodality MR and temperature mapping with the pathological results and to determine the role of imaging in predicting histological outcomes of transrectal focal laser ablation therapy in the treatment of localised prostate cancer.

Study design

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

Intervention

Patient group A will undergo additional MR-guided focal laser ablation before they undergo radical prostatectomy and patient group B will receive MR-guided focal laser ablation as main therapy for their prostate cancer

Study burden and risks

Potential patient risks in this study as mentioned by complications of MR-guided focal laser ablation (hemorrhage, inflammation, minute risk of perforation of urethra or bladder, and fistula formation) or of MR-guided biopsy (hemorrhage, inflammation, minute risk of perforation of urethra or bladder) of magnetic resonance imaging (burden of heating and noise, risks of contrast reactions against gadolinium) or serious unexpected events and patient burden in form of time investment are outweighed by potential benefits for patients. Patients in group B have a great chance to stay potent and continent, which is a great benefit of this treatment.

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

Inclusion criteria counting for both groups:
• Newly diagnosed and biopsy proven prostate cancer
• Low risk patients (PSA <= 10 ng/mL, Gleason 3+3, cT1c - T2a)
• No previous treatment for prostate cancer
• Cancer lesion located at least 2 cm away from the neurovascular bundle according to Multimodality MR images
• Signed informed consent by patient
• Age 18 years or older
• Signed screening form (to determine exclusion for metal device/foreign bodies/claustrophobia);Additional inclusion criterion for patients in group A:
• Patients must be scheduled for a radical prostatectomy with a lesion of max 4 cm

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 focal laser therapy (colitis ulcerosa, rectal pathology or abdomino perineal resection)
• Metallic hip implant or any other metallic implant or device that distorts local magnetic field and compromises the quality of MR imaging
• Patients with evidence for nodal or metastatic disease
• Patients with an estimated Glomerular Filtration Ratio (eGFR) < 40 mL/min/1.73 m2

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-03-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Visualase Laser Technology
Registration:	No

Ethics review

Approved WMO

Date:	22-03-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-05-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-04-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-11-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-02-2015
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
CCMO	NL32695.091.10