Multi-center MRI-guided focal laser ablation of prostate cancer.

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

Summary

ID

NL-OMON44447

Source
ToetsingOnline

Brief title
MRI-guided focal laser ablation

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Malignant adenocarcinoma of the prostate, Prostate cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Focal laser ablation (FLA), Magnetic resonance imaging (MRI), Prostate cancer, Robot-guided laser-induced interstitial thermal therapy (LITT)

Outcome measures

Primary outcome

The oncologic safety (PSA measurements at 6 weeks, 3, 6, 12 and 24 months; MR imaging at 6, 12 and 24 months; and*targeted and random systematic 12-core biopsy at 12 months post focal therapy), functional outcome, complication rates (i.e. urinary incontinence, irritative/obstructive bowel and erectile dysfunction), re-treatment percentage, the EORTC QLQ-PR25 scale for sexual symptoms, ICIQ (incontinence), IPSS (urinary problems) and SHIM IIEF-5 (erectile dysfunctioning), success rate, complication rates (according to Clavien system for surgical complications), operating time and hospital stay.

Secondary outcome

Not applicable.

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 perform a multicenter study on magnetic resonance imaging (MRI) and robot-guided laser-induced interstitial thermal therapy (LITT) of prostate cancer or in short focal laser ablation (FLA). FLA holds the promise to provide a faster, less expensive and less invasive alternative to radical prostatectomy with also less side effects. Seventy-three patients with low to intermediate-risk localized prostate cancer, will get the focal therapy as main treatment. Potential complications will be recorded and diagnostic MRI and MRI-guided biopsy results will be used to assess the treatment success

rate.

Study objective

The primary objective for this trial is to assess the local cancer control achieved with FLA in patients with localized low to intermediate risk prostate cancer (Gleason 3+3, 3+4 or Gleason 4+3).
Secondary objectives are to determine effectiveness of FLA in men with prostate cancer in terms of functional outcome, quality of life and complication rates.

Study design

A prospective, non-randomized, multi center study. This trial will be coordinated by the Radboud University Medical Center. Patient recruitment will take place at the Radboudumc (Nijmegen, The Netherlands), Alma Clinic (Paris, France) and Sørlandet Sykehus Kristiansand (Norway) from February 2018 to February 2020. The multiparametric MRI and the MRI and robot-guided FLA will be performed at the site of inclusion.

Intervention

Patients will receive MRI and robot-guided focal laser ablation as main prostate cancer treatment.

Study burden and risks

Possible complications associated with focal laser ablation are hemorrhage, inflammation, minute risk of perforation of urethra or bladder, and fistula formation. The use of MRI-guidance may have a burden of local heating and noise, risks of contrast reactions against gadolinium, or serious unexpected events and patient burden in form of time investment. These drawbacks are outweighed by potential benefits for patients.

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

1. MRI visible index lesion (on T2-weighted MR imaging or diffusion weighted imaging)
2. maximum MRI visible lesion size is <<= 15 mm large axis
3. 45 to 76 years old patient
4. life expectancy at the inclusion of more 10 years
5. underwent systematic TRUS-guided biopsy
6. diagnosis of prostate cancer confirmed by targeted biopsy using TRUS-MRI fusion or in-bore
MRI guided biopsies
7. criteria of low and intermediate risk of progression and eligibility for focal therapy
a. a clinical stage of maximum T2c
b. a maximum biopsy Gleason score of 4 + 3 on targeted biopsies
c. a serum prostate specific antigen < 15 ng/ml
8. patient accepting to be included in an active surveillance protocol at the end of the study, in
accordance with the recommendations of good practice

Exclusion criteria

1. history of prostate surgery
2. history of radiation therapy or pelvic trauma; history of proved acute or chronic prostatitis
3. history of tumor in the preceding 5 years (excluded: non-metastatic basal cell skin cancer)
4. severe urinary symptoms associated with benign hyperplasia of the prostate, and defined by an

IPSS score > 18
5. tumor with MRI signs of extra-capsular extension or invasion of the seminal vesicles
6. maximum cancer core length >3 mm and/or maximum Gleason score of 3+4 on systematic
biopsies outside the visible tumor area on mpMRI
7. Impossibility to obtain a valid informed consent
8. Patients unable to undergo MR imaging, including those with contra-indications
9. Contra-indications to MR guided focal laser therapy (colitis ulcerosa, rectal pathology or abdomino perineal resection)
10. Metallic hip implant or any other metallic implant or device that distorts local magnetic field and
compromises the quality of MR imaging
11. Patients with evidence for nodal or metastatic disease
12. Patients with an estimated Glomerular Filtration Ratio (eGFR) < 40 mL/min/1.73 m2

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-10-2018
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Soteria Remote Controlled Manipulator (RCM)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-08-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-02-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-09-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-05-2020
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	NL63647.091.17