Magnetic resonance imaging-guided focal laser ablation of prostate cancer

Published: 07-12-2021
Last updated: 06-05-2024

Primary objectiveThe primary objective for this phase IIa study is to investigate the feasibility, usability and safety of CLS MR-guided FLA in the treatment of prostate cancer.Secondary objectiveTo assess tumor response and functional outcomes

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

Summary

ID

NL-OMON54136

Source
ToetsingOnline

Brief title
MRI-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: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Clinical Laserthermia Systems AB (CLS AB),Radboudumc en CLS (bedrijf)

Intervention

Keyword: Focal laser ablation, MRI-guided, Prostate cancer

Outcome measures

Primary outcome

Main study parameter/endpoint

• Technical success, as determined by:

o Completion of the laser ablation without technical failures

o Achievement of complete ablation shown by MRI after treatment calculated using image co-registration software.

• Total procedure time

• Total number of fiber positions and ablations needed

• Procedure-related adverse events and complications following SIR criteria

Secondary outcome

• Tumor response measured with MRI 6 months after treatment (Lack of enhancement on dynamic contrast enhanced MR imaging in the treated area)

• Progression free survival at 6 months

• Functional outcome (i.e. urinary incontinence, and erectile dysfunction). The IPSS and IIEF-5 (erectile dysfunctioning) at 6 weeks, 3, 6 and 12 months.

• Complication rates according to SIR system

• Local progression free survival

Study description

Background summary

Prostate cancer is the most frequent non-cutaneous malignancy in the western male population, with almost 13,600 newly diagnosed patients in the Netherlands in 2019 (1). Due to widespread use of the prostate-specific antigen (PSA) test and the lowered PSA threshold for biopsy, the number of newly diagnosed prostate cancers strongly increased in the last 20 years (2).
At present, treatment choice for prostate cancer patients at low or intermediate risk of disease progression lies between active surveillance (AS) and radical therapies, such as radical prostatectomy or radiotherapy. For these patients, radical treatments have a comparable effectiveness, with a risk of specific death of less than 1% in 15 years. However, none is devised of consequences on the quality of life and can induce significant morbidities such as incontinence and impotence (3-5).
For this reason, innovative ablation techniques such as cryosurgery, high intensity focused ultrasound, photodynamic therapy and laser ablation therapy have emerged and are increasingly applied in clinical practice. These treatment methods aim for local destruction of cancerous cells using various sources of energy (6). The main advantage of preservation of healthy prostatic tissue is to reduce treatment-related complications and morbidity (7). Recent studies demonstrate that post-treatment prognosis is predominantly driven by the largest lesion with the highest grade, the so-called *index lesion* (7, 8).
Treatment approaches which preserve parts of the prostatic gland are considered as focal therapy. Imaging plays an important role in detection, localization, targeting and monitoring of focal prostate cancer treatment. Multi-parametric magnetic resonance imaging (mpMRI) is preferred in detecting and staging prostate cancer due to excellent soft tissue contrast and multiplanar anatomical imaging (9, 10). It is also used to differentiate between post-treatment changes and potential recurrent or residual disease. As such, secondary treatment can be promptly established (11). More recently, mpMRI has gained acceptance in image-guided therapeutic settings since it offers real-time anatomical imaging in different planes and therefore improved treatment accuracy (12). Furthermore it can provide real-time temperature imaging.
Focal laser ablation (FLA) or laser-induced interstitial thermal therapy (LITT) is a relatively new technique which was originally developed to treat brain tumors. During this therapy, a laser fiber is positioned into the tumor under image guidance (ultrasound or MRI). When the position of the fiber is correct, laser light is delivered through the fiber and the temperature of the tissue around the tip of the fiber increases. When temperature increases above 60°C the tissue is irreversibly damaged and destroyed. The total ablation process takes about 2-3 minutes. MRI is perfectly suited to use for image guidance during FLA, because it can be used to localize the tumor, target it with probes, monitor and control the ablation procedure in real-time and to map tissue temperature.
Only a few studies on MRI-guided FLA are known. Lepor et al provided a pilot study of 25 patients with low-intermediate risk prostate cancer undergoing FLA. Three months after treatment, they showed no significant differences in functional outcome according to the SHIM (Sexual Health in Man) and AUASS

(American Urological Association Symptom Score) questionnaires and no incontinence. Furthermore, 96% of the ablation zones targeted with biopsy three months after treatment, showed no histopathological prove of residual prostate cancer. A recent study by Walser et al. demonstrated a freedom of retreatment rate of 83% after a one year follow up in a group of 120 men with low- to intermediate risk disease that underwent transrectal FLA with no significant changes in quality of life or sexual and urinary function (15).
In Radboudumc we have several years of experience with MRI-guided focal laser ablation for prostate cancer treatment. At this moment separate systems are used for MR thermometry (IFE, Siemens) and laser energy control (Biolitec). CLS offers a dedicated system which integrates laser energy control with MR thermometry for ablation monitoring. Next to this, additional types of laser fibers are available that are thought to produce relatively larger, more adequate ablation zones (up to 3.0 x 2.0 cm) in comparison to current fibers. In potential, this will decrease the total procedure time because less ablations per lesion are needed and more patients will be eligible for FLA because larger tumors can be treated.
This project has the purpose to assess the feasibility of MRI-guided FLA treatment using the newly developed CLS system as well as its usability and safety.

Study objective

Primary objective
The primary objective for this phase IIa study is to investigate the feasibility, usability and safety of CLS MR-guided FLA in the treatment of prostate cancer.
Secondary objective
To assess tumor response and functional outcomes

Study design

Single-center, interventional treatment, non-randomized, open label, single arm, phase IIa study with a CE-labeled medical device. This phase 2 study will be coordinated by the Radboudumc. Patients will be recruited from patients presenting at the Radboudumc.

Intervention

MRI-guided focal laser ablation of prostate cancer

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, since FLA has a lower chance on developing impotence and incontinence when comparing it to the standard treatment of radical prostatectomy of radiotherapy.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• MRI visible index lesion (on T2-weighted MR imaging or diffusion weighted imaging); • maximum MRI visible lesion size is <= 20 mm large axis; • age 45 to 76 years old; • life expectancy at inclusion of more 10 years; • diagnosis of prostate cancer confirmed by targeted biopsy; • criteria of low and intermediate risk of progression and eligibility for focal therapy; o clinical

stage of maximum T2c o maximum biopsy Gleason score of 4 + 3 on targeted biopsies o serum prostate specific antigen < 15 ng/ml • 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

• History of prostate surgery; • history of radiation therapy or pelvic trauma; history of proved acute or chronic prostatitis; • history of tumor in the preceding 5 years (excluded: non-metastatic basal cell skin cancer); • severe urinary symptoms associated with benign hyperplasia of the prostate, and defined by an IPSS score > 18; • tumor with extra-capsular extension or invasion of the seminal vesicles; • patients with >2 lesions; • 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):	25-02-2022
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	11-05-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	13-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-05-2024
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	NL78437.091.21