

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Reproductive neoplasms male malignant and unspecified
<b>Study type</b>	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**

### **Public**

Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10

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NL

### **Scientific**

Radboud Universitair Medisch Centrum

## 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  $\leq 15$  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 m<sup>2</sup>

## 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