Transperineal Laser Ablation for Focal Prostate Cancer: Safety and Ablative Efficacy evaluation using post-radical Prostatectomy Histological Analysis

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

Summary

ID

NL-OMON48033

Source
ToetsingOnline

Brief title
TPLA for PCa

Condition

- Reproductive neoplasms male malignant and unspecified
- Urinary tract signs and symptoms
- Prostatic disorders (excl infections and inflammations)

Synonym
malign neoplasmata of the prostate, Prostate Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Elesta

Intervention

Keyword: Ablation, Cancer, Laser, Prostate

Outcome measures

Primary outcome

The main study parameter for histological ablative efficacy is assessed on histopathological analysis of the prostatic tissue after radical prostatectomy by means of the absence of vital cells in the treated prostate zone.

Secondary outcome

Secondary parameters are the determination of the ablation site by imaging modalities (CEUS and mpMRI) compared to the histopathological analysis. Secondary parameter for feasibility is the number of successful TPLA procedures and for safety is the number of grade 3 adverse events. Secondary parameters for functional outcomes are validated questionnaires.

Study description

Background summary

Prostate cancer (PCa) is the second cause of cancer-related deaths for men. The standard surgical treatment is radical prostatectomy. Possible side effects of this treatment are incontinence and erectile dysfunction. These side effects are especially undesired in patients with only a small focus of PCa. A focal treatment with fewer side effects is desired. Focal laser ablation is an investigated technique for local treatment. Downside is the single fibre setup of most systems with the need for fibre replacement and the in-bore application. This leads to longer treatment duration and thus higher costs. The Echolaser® system is a laser ablation system with four laser sources. This

provides a potential larger treatment area, without the need for fibre replacement. This makes the system ideal for focal laser ablation of prostate cancer, especially since it can be applied under local anaesthesia.
This pilot study aims to prove feasibility, safety and histological ablative efficacy of transperineal laser ablation using a (multi)fibre setup in men with localized prostate cancer.

Study objective

The primary objective of this study is to determine histological ablative efficacy by absence of vital (tumour) cells in the treated prostate zone with (multi)fibre setup in men with PCa scheduled for radical prostatectomy. The secondary objectives are to determine the size of the ablated area using single or multiple laser fibres and tissue changes seen on imaging modalities (CEUS and mpMRI), compared with histological changes, safety and feasibility, and finally functional outcomes.

Study design

This study is set up as a prospective, multicentre, interventional pilot study. This study is an ablate and resect study meaning that TPLA treatment under local anaesthesia is followed by radical prostatectomy approximately four weeks following laser treatment. We aim to perform 9 procedures in 9 patients.

Intervention

All subjects undergo a transperineal laser ablation of their prostate under local anaesthesia using the Echolaser® system. One or two laser fibres are placed in the prostate inducing coagulative necrosis. Several fibre configurations are used during the ablation in subsequent patients (one or two fibres and at a distance of 5 and 10mm).
Complete tumour ablation is an aim of this study, provided proper safety margins and visibility on imaging. However, this is not the main aim of this study.

Study burden and risks

The risks for participation in this study are related to the TPLA procedure. As this is an ablate and resect study, patients do possibly not benefit from the TPLA treatment, because TPLA is followed by radical prostatectomy. Patelli et al. demonstrated that the TPLA procedure treatment of BPO is associated with minimal risks.
Several precautions will be taken to reduce the patients* risk. The fibres are placed under permanent ultrasound guidance for safety margin control and treatment will be performed more central in the prostate, while maintaining a safe distance to the rectal wall and urethra. Furthermore, TPLA will be

performed under antibiotic prophylaxis to prevent infection. In addition, TPLA is a minimal invasive approach that requires only local anaesthesia and sedation is optional. Thus, the patient does not need additional anaesthesia for the TPLA treatment.
Follow-up consists of two outpatient visits and one call by telephone. The outpatient visits include one prostate ultrasound imaging investigations with a contrast enhancing agent, one mpMRI and completion of continence and erectile function questionnaires.
In conclusion, TPLA does not benefit the patient and the patient is exposed to possible risks of TPLA treatment. However, risks of TPLA treatment are minimal due to the minimal invasive approach and central treatment. Follow-up includes one call by telephone and two visits, one mpMRI and one contrast enhanced ultrasound. We argue that the histopathological and imaging outcomes of this study are an essential basis for future focal laser PCa treatment. Therefore, the burden of this study is acceptable when patients are informed adequately. This ablate and resect regimen has already been applied in the Amsterdam UMC and Athens using IRE (irreversible electroporation) as a focal treatment approach for prostate cancer that formed the basis for further prospective studies.

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

- Male
- *40 years of age
- Histopathological confirmed organ-confined prostate cancer
- Indication for a radical prostatectomy
- Prostate volume *40mL
- Ability of the patient to stop anticoagulant therapy according to standard hospital pre-operative protocol
- Signed informed consent

Exclusion criteria

- Prior or concurrent treatment for prostate cancer (biologicals, chemotherapy, radiotherapy)
- Inability or unwillingness to tolerate temporary discontinuation of anticoagulation or anti-platelet therapy
- Other conditions / status

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2020

Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	Echolaser X4
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-09-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL69903.018.19