# The Safety and Efficacy of Irreversible Electroporation for the Ablation of Prostate Cancer Assessed by Procedural Related Side Effects and Post Prostatectomy Histology: A Prospective Human In-Vivo Study

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To evaluate the safety, efficacy and to acquire data on patient experience of minimally invasive, percutaneous, image guided IRE for the ablation of prostate cancer.

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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-OMON39362

**Source**
ToetsingOnline

**Brief title**
IRE-Prostate

### Condition

- Reproductive neoplasms male malignant and unspecified

**Synonym**
Prostate cancer, Prostatic neoplasm

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Clinical Research Office of the Endourological Society (CROES)

## Intervention

**Keyword:** Focal Therapy, Irreversible Electroporation, NanoKnife, Prostate Cancer

## Outcome measures

### Primary outcome

a) To determine if the IRE ablation procedure is safe as measured by the composite number of procedural, device and post procedural adverse events measured with the CTCAE proforma.

b) To determine if complete ablation of the specified targeted ablation zone is achieved as measured by histopathology assessment.

### Secondary outcome

a) To determine if procedural side effects associated with current treatments for prostate cancer, mainly incontinence, erectile dysfunction and bowel damage are avoided as measured by the validated prostate cancer scores *EPIC, IIEF-5 and IPSS or time of CAD required.

b) To determine patient satisfaction and comfort measured by Patient Satisfaction Questionnaire, post procedural pain management and pain scores, time to ambulation, length of hospital stay.

c) To determine accurateness of ablation zone detection by MRI/CEUS.

# Study description

## Background summary

Current surgical and ablative treatment options for prostate cancer have a relatively high incidence, up to 90%, of incontinence, erectile dysfunction and bowel damage. These side effects diminish the quality of life of prostate cancer sufferers and impact on patients* decision to undergo early, potentially curative treatments. These side effects are due to procedure related damage of the blood vessels, bowel, urethra and/or neurovascular bundle. New treatments that limit damage to these structures have the potential to improve patient outcomes. Ablation with Irreversible Electroporation (IRE) has been shown to be effective in destroying tumour cells and to have the advantage of sparing surrounding tissue and vital structures such as blood vessels and neurones.

## Study objective

To evaluate the safety, efficacy and to acquire data on patient experience of minimally invasive, percutaneous, image guided IRE for the ablation of prostate cancer.

## Study design

Prospective Human In-Vivo study: Up to 16 patients with confirmed low- or intermediate risk prostate cancer scheduled for a radical prostatectomy will be asked to have the IRE procedure approximately 30 days prior to the prostatectomy. Ablation with IRE will be performed using similar planning criteria, procedure protocol, instruments and software used for brachytherapy. Patients will have an ultrasound of the prostate and the imaging data will be entered into the Planning Software system. The patients will be admitted for overnight stay in the hospital on the morning of the scheduled IRE procedure. The IRE will be performed under general anaesthetic and the specified zone identified in the planning stage will be ablated. Safety data will be collected and patients will be followed up at 1 week, 2 weeks post IRE, pre-prostatectomy, post prostatectomy and 1 week post prostatectomy. The safety data collection is at 2 weeks post IRE. Before the prostatectomy patients will have a MRI and CEUS of the prostate. The patients will have their scheduled prostatectomy at approximately 30 days after the IRE procedure. Pre-prostatectomy, the ablation zone will be radiologically assessed by MRI/CEUS. Post prostatectomy, efficacy of ablation will be determined by histological examination of the prostate by the AMC Pathology Department and measured as complete or incomplete ablation.

The primary outcome is safety as measured by the composite of procedural device and post procedural adverse events, measured with the Common Terminology Criteria for Adverse Events v 4 (CTCAE), Expanded Prostate Cancer Index Composite (EPIC) score, International Prostate Symptom Score (IPSS) or required catheterization time and International Index of Erectile Function (IIEF) and

efficacy of ablation determined by histological examination post prostatectomy. Secondary outcomes will be patient*s procedure satisfaction measured by patient satisfaction questionnaire, post procedural pain management and pain scores, time to ambulation, length of hospital stay.

### Intervention

Ablation with IRE will be performed using similar planning criteria, procedure protocol, instruments and software used for brachytherapy, a conventional targeted radiation therapy where radioactive seeds are implanted into prostate tumours. Patients will have an ultrasound of the prostate and the imaging data will be entered into the Planning Software system. The volume of the prostate is measured and a specified ablation zone will be determined. The patients will be admitted for overnight stay in the hospital on the morning of the scheduled IRE procedure. The IRE will be performed under general anaesthetic and the specified zone identified in the planning stage will be ablated. Two IRE electrode needles will be placed into the prostate under ultrasound image guidance. When the needles are in place, electric pulses of one to two minutes duration are used to ablate the specified zone. The total procedure time will be approximately 1 hour.

### Study burden and risks

Electroporation is a technology that sends high voltage direct current pulses through the prostate. These pulses function in between the two electrodes and therefore work locally. However, in patients with a cardiac premedical history, there is a possibility that they can cause an arrhythmia. Therefore, these patients are excluded from the study. Further potential risks and danger are: Infection, bleeding, (temporarily) anuria requiring catheterization, urethral stricture, (temporarily) pain in the treated area, (temporarily) hematuria, (temporarily) zwelling of the scrotum, (temporarily) incontinence.

There is no direct advantage for the patient to take part in this study. The advantage of participation is the knowledge that people in the future can receive a tailored treatment for prostate cancer with less side effects. For this study, an extra intervention under narcosis is required. The risk are limited, because the prostate will be removed in toto 4 weeks after treatment. The study is of great importance for validation of the technology for prostate cancer 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

1. Life expectancy > 10 years
2. Histologically confirmed organ-confined prostate cancer (clinical stage T1-T2)
3. Gleason score *7
4. PSA <20 ng/ml
5. Able to visualize prostate gland adequately on transrectal US imaging
6. No prostate calcification greater than 5 mm
7. Ability of subject to stop anticoagulant and anti-platelet therapy for 7 days prior and 7 days post procedure

## Exclusion criteria

1. Other Conditions/Status:
a) Bleeding disorder as determined by prothrombin time (PT) > 14.5 seconds, partial thromboplastin time (PTT) > 34 seconds, and Platelet Count < 140/uL
b) Active urinary tract infection (UTI)
c) History of bladder neck contracture
d) Anaesthesia Surgical Assignment, category IV

e) History of inflammatory bowel disease
f) Concurrent major debilitating illness
g) Prior or concurrent malignancy
h) Cardiac History
i) ICD / Pacemaker
2. Prior or current therapies
a) Biologic therapy for prostate cancer
b) Chemotherapy for prostate cancer
c) Hormonal therapy for prostate cancer within 3 months of procedure
d) Radiotherapy for prostate cancer
e) Transurethral prostatectomy (*TURP*), urethral stent
f) Prior major rectal surgery (except haemorrhoids)
g) Inability or unwillingness to tolerate temporary cessation of concurrent anticoagulation therapy or anti-platelet drugs for a period of 7days prior to procedure and up to 7 days after procedure

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 07-08-2013 |
| Enrollment: | 10 |
| Type: | Actual |

## Medical products/devices used

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|---|---|
| Generic name: | NanoKnife Irreversible Electroporation System |
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 18-12-2012 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 07-01-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 01-07-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 11-11-2013 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 25-11-2013 |
| 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 | NL40870.018.12 |