# Efficacy of MRI-guided Prostate Irreversible Electroporation (IRE) therapy; the EMPIRE-trial.

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Assessment of disease control, and genito-urinary and rectal side effects, in patients with localized prostate cancer, 24 months after focal IRE therapy.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Prostatic disorders (excl infections and inflammations) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON46509

**Source**
ToetsingOnline

**Brief title**
EMPIRE-trial

### Condition

- Prostatic disorders (excl infections and inflammations)

**Synonym**
Prostate Cancer, Prostate Malignancy

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Sint Antonius Ziekenhuis
**Source(s) of monetary or material Support:** St. Antonius Innovatiefonds

## Intervention

**Keyword:** Focal therapy, Irreversible Electroporation Therapy, Localized, Prostate Cancer

## Outcome measures

### Primary outcome

- Assessment of urinary incontinence in patients with localized PCa, 24 months after focal IRE therapy, measured by EPIC-26 questionnaire.

### Secondary outcome

- Assessment of genito-urinary and rectal side effects in patients with localized PCa after focal IRE therapy, measured by IPSS-QoL, EPIC-26, IIEF-15, EQ-5D, EORTC-QLQ-C30&PR25, SHIM, HADS, ICIQ and WAI.
- Assessment of disease control in patients with localized PCa after focal IRE therapy, measured by mp-MRI 12 months after IRE therapy, by re-biopsy after 12 months, and by periodic PSA testing.
- Assessment of the utilization of mp-MRI in patients with localized PCa after focal IRE therapy, to evaluate ablation zone periodically, by mpMRI after 12 months.
- Assessment of complications in patients with localized PCa after focal IRE therapy, measured by the Clavien-Dindo classification of surgical complications.

# Study description

### Background summary

Yearly, 11.000 men are diagnosed with prostate cancer (PCa) in the Netherlands. Mostly, men are diagnosed with localized disease. Focal therapy is a novel

alternative to current, widely-used, radical whole-gland therapies (radical prostatectomy or radiotherapy). Radical therapy significantly reduces long-term functional outcomes, leading to detrimental results on quality of life. Irreversible electroporation (IRE) therapy is an emerging focal therapy, relying on a non-thermal mechanism to induce cell-death. Early clinical outcome in literature shows low impact on continence and potency. Oncological outcomes on short-term are good, but long-term follow up has yet to be evaluated.

### Study objective

Assessment of disease control, and genito-urinary and rectal side effects, in patients with localized prostate cancer, 24 months after focal IRE therapy.

### Study design

Prospective, single-arm intervention study.

### Intervention

Patients will undergo IRE as focal treatment for PCa.

### Study burden and risks

The nature and extent of burden associated with participation consists of 3-4 extra visits to the hospital.
- Patients will firstly visit extra for inclusion. Patients will fill out questionnaires a total of six times.
- If not performed yet, before IRE treatment, patients will have to undergo Transperineal Template-guided biopsies (TTMB) of the prostate for adequate tumour localisation.
- Subsequently, patients will undergo focal IRE ablation therapy, planned as an overnight-stay procedure, under general anaesthetics.
- In concordance with the Active Surveillance protocol, after 12 months, patients will undergo another mpMRI and after 12 months another prostate biopsy session, to guarantee adequate disease control.

Lifelong periodic control, including PSA measurement, will be performed for PCa regardless of the study.

Potential benefits for the patients are better long-term functional outcome results and equal oncological outcome results compared to whole-gland radical therapy of PCa. Earlier described risks of participation and IRE treatment are transient haematuria, urinary tract infection/urosepsis, (worsening of) erectile dysfunction, (worsening of) lower urinary tract symptoms, urinary retention, perineal hematoma, or urethra damage or rectal damage. When PCa is not properly treated with focal therapy, patients might undergo an additional

IRE procedure or a radical treatment eventually. Based on the currently available publications on IRE therapy and target biopsy of the prostate the risk of complications is estimated to be low.

# 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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Signed written informed consent
- Age >40 years, and life expectancy of *10 years.
- Serum PSA <15ng/mL.
- Histologically proven low- to intermediate-risk PCa (i.e. Gleason *7 with max 3+4<=7).
- Localized disease (i.e. no extracapsular extension, vesiculae seminalis invasion or

suspected metastasis).
- Stage radiological *T2cN0M0 on mp-MRI, with *1 visible and histology proven lesion(s) in the prostate (PI-RADS 3-5). Co-existing MRI-unvisible Gleason 6 disease is no exclusion
- Prostatic lesion visible on mp-MRI, accessible for IRE with a maximum diameter of 20mm in the transversal plane.

### Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Patients who are unwilling to sign written informed consent
- Patients with ASA *4
- Patients with evidence of lesions in contact with the prostatic capsule on mpMRI.
- Patients with evidence of metastatic or nodal disease outside the prostate on mpMRI.
- Patients with GS >7.
- Patient with capsular contact of tumour *6mm in the prostate.
- Patients with previous treatment for PCa.
- Patients with a history of radiotherapy to the pelvis.
- Patients with a history of androgen suppression/hormonal therapy.
- Patients unable to undergo a TRUS.
- Patients who meet exclusion criteria for MRI following the protocol of the radiology department of the St. Antonius Hospital.
- Patients fulfilling the exclusion criteria for the Gadovist gadolinium (Glomerular Filtration Rate (GFR) of < 30 mL/min/1.73m2.
- Patients who underwent a transurethral resection of the prostate (TURP) or stenting of the prostate.
- Patients with bleeding disorders or the inability to stop anticoagulant or antiplatelet therapy.
- Patients with heart arrhythmia or an ICD or Pacemaker.

## Study design

### Design

**Study type:** Interventional

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 04-12-2018 |
| Enrollment: | 40 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 21-06-2018 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

## 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 | NL64381.100.17 |