The efficacy and safety of Irreversible Electroporation for the ablation of Small Renal Masses: A prospective in-vivo pilot study

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Primary Objectives:- To determine the clinical efficacy of IRE ablation of small renal masses (* 4cm), assessed by calculating recurrence and residual disease at follow-up, measured through the (non-)presence of tumour enhancement on cross-sectional...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal and urinary tract neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON46982

Source
ToetsingOnline

Brief title
Efficacy and Safety of IRE for SRMs.

Condition

- Renal and urinary tract neoplasms benign

Synonym
renal cancer, Renal Cell Carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum (AMC)

Source(s) of monetary or material Support: cure for cancer

Intervention

Keyword: (Small) Renal Masses ((S)RM), Ablation, Irreversible Electroporation (IRE), Renal Cell Carcinom

Outcome measures

Primary outcome

Primary study parameter:

- Clinical efficacy of IRE ablation of small renal masses (* 4cm), assessed by calculating recurrence and residual disease at follow-up, measured through the (non-) presence of tumour enhancement on cross-sectional imaging post IRE

Secondary outcome

Secondary study parameters:

- Safety of IRE ablation of small renal masses (* 4cm), by evaluating device and procedural adverse events using CTCAE v4.0

- CT, MRI and CEUS in the imaging of ablation success, extend of the ablation zone, 1 week, 3 months, 6 months, and 1 year post IRE

- Peri-operative outcomes after IRE ablation of small renal masses (* 4cm), such as renal function, measured by creatinine levels and eGFR pre- and post-operative, proteinuria, average length of hospital stay, average operation time, and pain level after IRE, measured by VAS and analgesics use

Study description

Background summary

The past two decades have shown a steady increase in the incidence of small

renal masses (SRM) up to 4 cm. This is in part the result of an increased use of abdominal imaging for non-urological complaints leading to incidental renal tumour detection. Nephron sparing surgery, in the form of partial nephrectomy, is considered to be the gold standard for treatment of SRMs. Currently thermal focal therapies such as cryoablation and radiofrequency ablation (RFA) are primarily recommended in patients who are poor surgical candidates or have a genetic predisposition for developing multiple tumours. Recent studies have shown 5-10 year oncological follow-up of cryoablation and RFA to be slightly inferior to partial nephrectomy, balanced by a lower complication rate. Promising long-term results combined with little or no loss in renal function have created interest in thermal focal therapies as a future treatment option for a broader range of patients. Focal treatment of tumours requires precisely dosed and accurate ablation of unwanted tissue while reserving surrounding healthy tissue and vital structures such as blood vessels, nerves, the renal collecting system and neighbouring organs. The unselective destruction of thermal ablation can result in damage of vital structures in the vicinity of the tumour. Thermal ablation intensity can be impaired due to *thermal sink*. The vicinity of large vessels and the renal collecting system causes thermal fluctuations leading to inconsistent ablation results.

Study objective

Primary Objectives:
- To determine the clinical efficacy of IRE ablation of small renal masses (* 4cm), assessed by calculating recurrence and residual disease at follow-up, measured through the (non-)presence of tumour enhancement on cross-sectional imaging post IRE
Secondary Objectives:
- To determine the safety of IRE ablation of small renal masses (* 4cm), by evaluating device and procedural adverse events using CTCAE v4.0
- To evaluate the use of CT, MRI, and CEUS in the imaging of ablation success, extend of the ablation zone, 1 week, 3 months, 6 months, and 1 year post IRE
- To evaluate peri-operative outcomes after IRE ablation of small renal masses (* 4cm), such as renal function, measured by creatinine levels and eGFR pre- and post-operative, proteinuria, average length of hospital stay, average operation time, and pain level after IRE, measured by VAS and analgesics use

Study design

This is a prospective, human, in-vivo, pilot study.

Intervention

Patients will receive IRE ablation of the SRM, performed under general anaesthesia. Follow-up will be performed using CT, MRI, and CEUS at 1 week, 3

months, 6 months, and 1 year post IRE.

Study burden and risks

Conventional focal ablative therapies, RFA and cryoablation, are indicated in patients presenting with a solid enhancing small renal mass who are poor surgical candidates. In this study IRE ablation will be offered to this group of patients. Early research into renal IRE have proven the procedural safety, and the peri-procedural burden, to be comparable to conventional ablative therapies. The lack of long term oncological follow up poses a potential risk as patients cannot be counselled on the risk of residual or recurrent tumour. Post IRE follow up will be equal to post cryoablation follow up and therefore does not pose additional burden with regard to ionizing radiation. When renal function appears to decrease, only MRI and CEUS will be performed to prevent kidney failure.

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

- Age * 18 years
- Solid, enhancing mass on cross sectional imaging
- Signed informed consent
- Candidate for focal ablative therapy

Exclusion criteria

- Irreversible bleeding disorders
- Anaesthesia Surgical Assignment (ASA), category * IV
- ICD / pacemaker
- Severe cardiovascular disease in medical history

Study design

Design

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):	25-07-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Irreversible Electroporation;Nano Knife

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-05-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-07-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-07-2018
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	NL56935.018.16