The Efficacy and Safety of Irreversible Electroporation for the Ablation of Renal Masses: A Prospective, Human, In-Vivo Study.

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Primary Objectives:- To determine the efficacy of IRE ablation of renal masses, measured by histopathologic examination of the targeted tumour.- To determine the safety of IRE ablation of small renal masses, by evaluating device and procedural...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON40514

Source
ToetsingOnline

Brief title
Efficacy and Safety of IRE for RMs.

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
renal cancer, renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

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

Outcome measures

Primary outcome

1. The efficacy of IRE ablation of renal masses, measured by histopathologic examination of the target tumour by an experienced genitourinary pathologist. Using immunehistochemical staining to evaluate cell viability.

2. The safety of IRE ablation of renal masses, by evaluating device and procedural adverse events using CTCAE v4.0.

Secondary outcome

- The efficacy of MRI in the imaging of ablation success, extend of the ablation zone, one and three weeks post IRE ablation. By comparing MRI imaging to the histopathological examination results of the resected material.

- The efficacy of CEUS in the imaging of ablation success, extend of the ablation zone, one and three weeks post IRE ablation. By comparing CEUS imaging to the histopathological examination results of the resected material.

Study description

Background summary

The past decades have shown an increase in the incidence of small renal masses

(SRM). At the moment laparoscopic partial nephrectomy is the *golden standard* in treatment of SRMs. Thermal ablation techniques are indicated in patients who are poor surgical candidates or who have a predisposition to develop multiple tumours. Recent studies have shown thermal ablation techniques to have similar long-term oncologic results. Downsides to thermal ablation are the possible damage to vital structures in the vicinity of the ablation zone, e.g. collecting system or intestine, and unpredictable results due to difficulty in monitoring the ablation zone and *thermal sink*.

Electroporation or electropermeabilisation is a novel technique with the potential to overcome the main disadvantages of thermal ablation. It utilizes electric pulses, traveling between two or more electrodes, to create *nanopores* in the cell membrane. If the applied current reaches a certain threshold these *nanopores* become permanent resulting in cell death. The use of electric current means that IRE is not susceptible to *thermal sink* leading to consistent ablation results. IRE ablation targets the cell membrane, sparing tissue architecture and minimizing damage to blood vessels, nerves and the renal collecting system.

The first in human studies have proven the safety of IRE for the ablation of small renal masses. However the efficacy of IRE through histopathological examination of an ablated renal tumour has not yet been studied, compromising the correct and scientific evaluation of a new technology. This is the primary objective of this research project.

Study objective

Primary Objectives:
- To determine the efficacy of IRE ablation of renal masses, measured by histopathologic examination of the targeted tumour.
- To determine the safety of IRE ablation of small renal masses, by evaluating device and procedural adverse events.

Secondary Objective:
- To evaluate the efficacy of MRI in the imaging of ablation success, extend of the ablation zone, one and three weeks post IRE ablation.
- To evaluate the efficacy of CEUS in the imaging of ablation success, extend of the ablation zone, one and three weeks post IRE ablation.

Study design

This is a prospective, human, in-vivo pilot study. Patients will receive IRE ablation of the SRM, performed under general anaesthesia, 4 weeks before radical nephrectomy. Follow-up at one and three weeks post IRE will be performed using MRI and CEUS imaging. After radical nephrectomy histopathological examination will be performed to evaluate IRE ablation

success.

Intervention

Patients will undergo IRE ablation of a renal tumour. The IRE procedure will take place at the Intervention Radiology room at the OR complex under general anesthesia with aditional muscle relaxation. ECG monitoring and synchronization of IRE pulses will be performed. Needle electrodes will be placed under ultrasound guidance using an external spacer for fixation during pulse administration, between 3 and 5 electrodes will be used to adjust the ablation zone. Device settings will be kept at fixed settings while electrode number and placement will be adjusted for specific tumour shape and size. Pulses will be administered in sets of 10 after which the device will recharge for 3.5 seconds. The IRE treatment cycle will take several minutes, total operating time is estimated at 2 hours.

Study burden and risks

There are no benefits for patients that participate in this study.

Study participants will be exposed to additional risk when compared to standard treatment. They will have to undergo an additional procedure under general anaesthesia with muscle relaxation. Patients have to be informed about the risks of procedural complications as noted in paragraph 6.4. The exposure to ionizing radiation during the procedure has been estimated at 32 mSv.

Information on the efficacy of IRE, proven histopathologically, is a vital step in order to progress to long term follow-up studies without tumour excision. So far no study has investigated the efficacy of IRE for the ablation of renal tumours in this manner.

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
- Scheduled for a radical nephrectomy (open or laparoscopic)

Exclusion criteria

- Irreversible bleeding disorders
- Inability/unwillingness to interrupt anticoagulation therapy
- Previous cryoablation, RFA or partial nephrectomy in affected kidney
- Anasthesia 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:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	Irreversible Electroporation;Nano Knife
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	16-01-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	15-04-2014
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	NL44785.018.13