Bipolar-Multipolar Radiofrequency Ablation of Small Renal Masses (<=4cm)

Published: 16-12-2008
Last updated: 11-05-2024

To find an energy dose for the complete destruction of a renal tumour with bipolar-multipolar RFA.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Interventional

Summary

ID

NL-OMON35289

Source
ToetsingOnline

Brief title
RFA in SRM's

Condition

- Renal disorders (excl nephropathies)

Synonym
kidney cancer, renal cell carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Celon AG Medical instruments
Source(s) of monetary or material Support: Celon AG medical instruments (A member of the Olympus medical Systems Group)

Intervention

Keyword: RFA, SRM

Outcome measures

Primary outcome

Find an energy dose that allows a complete destruction of the tumour. Tumor destruction will be studied by histopathology-immunohistochemistry. These data will be correlated to the energy used.

Secondary outcome

none

Study description

Background summary

There is solid evidence that partial nephrectomy (excision) is as effective as radical (total) nephrectomy in the treatment of (srm*s=) small renal masses/tumors (<=4 cm). Until recently, an open operation was the gold standard approach. Laparoscopic partial nephrectomy is an emerging option. However, laparoscopic excision is technically very demanding and has to be performed under general anesthesia. Therefore an energy-based ablative technique that can eventually be applied percutaneously (image-guided) and under local anesthesia would be an important advancement. Two techniques i.e. cryoablation and radiofrequency ablation are currently being developed. To be fully acceptable for clinical application, the technique should ideally result in complete destruction of the tumor. Currently used cryoablation and monopolar RFA techniques have been shown to be feasible in the treatment of srm*s but complete destruction of the tumor cannot yet be achieved consistently.

Study objective

To find an energy dose for the complete destruction of a renal tumour with bipolar-multipolar RFA.

Study design

Dose finding study using a treat-and -resect protocol.

Intervention

Radiofrequency ablation (RFA) of the renal tumour in an open surgical setting followed by partial or total nephrectomy (treat-and-resect protocol)

Study burden and risks

The total time of the operation is prolonged by the time needed for the biopsy and the RFA. Complications of laparoscopic or percutaneous monopolar RFA are damage to the ureter and urinoma formation; these have been reported in 3-15% of the cases; bleeding was rarely seen [Klingler 2007]. Bipolar-multipolar RFA in an open setting, a well-known technique for the treatment of liver masses, is a new approach for the kidney, is likely to result in less complications.

Contacts

Public
Celon AG Medical instruments

Rheinstrasse 8
14513 Teltow
DE
Scientific
Celon AG Medical instruments

Rheinstrasse 8
14513 Teltow
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Pre-operative inclusion criteria
- Patient gives informed consent
- Patients with small renal mass [SRM] (<=4cm).
- The mass has to be a cortical tumor (not hilar)
Stop criterium
_ At the moment of procedure in case benign histology is found on frozen section biopsy, no RFA will be performed and the patient will not continue the study.

Exclusion criteria

- Pregnancy
- SRM > 4cm
- SRM in hilar area
- Clotting disorder or anticoagulant use that cannot be interrupted
- Benign histology at intraoperative biopsy

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):	18-05-2009
Enrollment:	15
Type:	Actual

Medical products/devices used

Generic name:	CelonProSurge (electrode);CelonLabPOWER (generator);CelonAquaflow III (pump)

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-12-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-09-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL22577.041.08