

Radio Frequency Ablation (RFA) of Renal Cell Carcinoma Prior to Nephron Sparing Surgery: A pilot study to assess completeness of ablation, accuracy of post-ablation imaging and the contribution of RFA to technical ease of the surgery

Submission date 29/09/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/10/2012	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

N0436165595

Study information

Scientific Title

Study objectives

The principal aims are to assess the completeness of the RF ablation and the accuracy of radiology imaging (with contrast enhanced ultrasound, CT and MRI) in assessing the tumour for residual RCC after treatment by correlation with pathological examination of the explanted specimen.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer: Renal

Interventions

1. 5 patients in the control group (surgery only)
2. 5 patients will undergo percutaneous RFA of their RCC 14 days before laparoscopic or open partial nephrectomy

Please note, the trial was stopped due to a lack of recruitment.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

The efficacy of RFA using the current technique in achieving complete tumour ablation will be assessed. Greater than 90% tumour destruction is desirable with the current technique. For contrast enhanced US, CT and MRI the positive predictive value in assessing tumour

destruction will be evaluated by correlation with the histological analysis of the explanted kidneys. Accuracy of greater than 80% for each test would be desirable and all modalities should be comparable in predicting tumour destruction

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/06/2007

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

10 candidates for partial nephrectomy ie with solitary RCC (less than 4 cm).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/06/2005

Date of final enrolment

01/06/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Radiology/Ultrasound Department
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Funder(s)

Funder type

Research organisation

Funder Name

Leeds Teaching Hospitals NHS Trust - NHS R&D Support Funding

Funder Name

CIRSE (Cardiovascular and Interventional Radiological Society of Europe)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration