ISRCTN33713464 https://doi.org/10.1186/ISRCTN33713464

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

Registration date
29/09/2006

Last Edited
16/10/2012

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Tze Wah

Contact details
Radiology/Ultrasound Department
Lincoln Wing
Beckett Street
Leeds
United Kingdom
LS9 7TF
+44 0113 206 4330
Tze.wah@leedsth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2005

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

Age group
Adult

Sex
Not Specified

Target number of participants
10

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration