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SURAB study: comparing ABlation with active SURveillance, in the management of incidentally diagnosed small renal tumours: a feasibility study

Submission date 25/07/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 25/07/2014	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 09/03/2020	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-treatments-for-small-kidney-cancers-surab

Contact information

Type(s)
Scientific

Contact name
Miss Ann Marie Hynes

Contact details
Clinical Trials Unit
Faculty of Medical Sciences
Newcastle University
1 – 4 Claremont Terrace
Newcastle upon Tyne
United Kingdom
NE2 4AE
+44 (0)191 208 7647
Ann.hynes@newcastle.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17090

Study information

Scientific Title
SURAB study: a randomised study comparing ABlation with active SURveillance, in the management of incidentally diagnosed small renal tumours: a feasibility study

Acronym
SURAB

Study objectives
The aim of this study is to establish whether a future definitive trial comparing active surveillance with ablative treatment for small kidney cancer is feasible. There is also a pre-pilot qualitative component to the study which will inform trial design.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1110701
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/115560/PRO-11-107-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/NE/0155; First MREC approval date 26/07/2014

Study design
Randomised; Interventional; Design type: Process of Care, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Cancer; Subtopic: Renal Cancer; Disease: Kidney

Interventions
Ablation, Currently, centres have tended to develop expertise in either cryotherapy or radiofrequency ablation; centres will therefore offer only one form of ablation (the one in which they have expertise). There will also be an opportunity for departments which offer microwave ablation to participate in the trial.; Active Surveillance, Participants will be monitored for the duration of the trial; Follow Up Length: 6 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The aim is to establish whether a future definitive trial comparing active surveillance with ablative treatment for small kidney cancer is feasible. This will be assessed quantitatively in terms of recruitment and retention rates and qualitatively in terms of the patients' experiences and understanding of the randomisation process and treatment options. Partition of reasons for loss to follow up, together with clinical data, will allow us to project likely retention at 5 years.

Secondary outcome measures
All secondary outcomes will be rehearsed during the pilot trial with a view to refining the choice of outcomes for the main trial, based on data yield and quality.
Outcome data collection in the pilot feasibility trial will be timed to coincide with routine clinical assessments and will collected from patients at 4,7 months post randomisation (3, 6 months post treatment).
The following secondary outcome questionnaires will be completed at baseline (within 14 days before randomisation) and at 3 and 6 months post treatment:
1. A general health questionnaire (SF-36)
2. Cancer specific health status and quality of life (FACT-G)
3. Anxiety and depression (STAI)
We have also developed and plan to test health economics data collection tools in the form of a participant costs questionnaire (PCQ). The PCQ has two parts: Part A to be administered at 3 month and 6 month and Part B at 6 month only.

Overall study start date
01/10/2014

Completion date
31/10/2016

Eligibility

Key inclusion criteria
1. Adult diagnosed with renal cancer < 4 cm (confirmation by radiology* or by biopsy)
2. ASA physical status classification system grade 1 or 2
3. Age =18 years of age
4. CT/MRI abdomen/chest with no evidence of metastases
5. Patient has provided written informed consent prior to any study specific procedures
*Radiological confirmation requires noting an enhancing renal mass of >20 Hounsfield units.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
Current exclusion criteria as of 09/03/2015:
Patients the clinician does not feel would be suitable for the trial (e.g., due to concomitant disease)
1. Multiple small renal cancers in one kidney
2. Coagulopathy that cannot be corrected
3. Previous participation in this study
4. Inability to give informed consent; carer/proxy consent will not be allowed in this study

Previous exclusion criteria:
Patients the clinician does not feel would be suitable for the trial (e.g., due to concomitant disease)
1. Fuhrman grade 3 / 4
2. Multiple small renal cancers in one kidney
3. Coagulopathy that cannot be corrected
4. Previous participation in this study
5. Inability to give informed consent; carer/proxy consent will not be allowed in this study

Date of first enrolment
01/04/2015

Date of final enrolment
29/02/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

For full details on participating centres please contact:
Clinical Trials Unit
Faculty of Medical Sciences
Newcastle University
1 – 4 Claremont Terrace
Newcastle upon Tyne
United Kingdom
NE2 4AE

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation (UK)

Sponsor details
CRO – Level 6; Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Our exact publication policy is not yet known although conference presentations and a peer-reviewed journal article/s are highly likely. We do not plan to inform patients of results on an individual basis; however, we will aim to disseminate findings to the public (and hence patients) through a range of mechanisms (peer review journal, conference presentations etc).

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2017		Yes	No
Plain English results			09/03/2020	No	Yes
HRA research summary			28/06/2023	No	No