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iSmaRT: Imaging small renal tumours

Submission date 30/08/2019	**Recruitment status** Recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 30/10/2019	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 03/05/2023	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-improving-the-assessment-of-kidney-treatment-ismart

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
iSmaRT - protocol v0.1 19/09/2018

Study information

Scientific Title
Dual source CT assessment of ablation success in renal tumours

Acronym
iSmaRT

Study objectives
Aims:
1. To assess if dual energy computed tomography (DECT) assessment of tumour vascularisation improves the diagnostic accuracy for residual disease and prediction of early recurrence following ablation of renal tumours.
2. To assess if evaluation of perfusion improves the sensitivity and specificity for residual disease compared to standard morphological assessment following small renal tumour ablation.

3. To assess if qualitative perfusion assessment with DECT (iodine mapping, iodine concentration) is comparable to quantitative perfusion CT (CTp) (BF,BV,PS) in distinguishing between ablation zone and residual disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/01/2019, London - City and East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT, UK; 0207 104 8026; nrescommittee.london-cityandeast@nhs.net), ref: 18/LO/2005

Study design
Prospective single centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Renal cancer

Interventions
Dual source computed tomography including dual-energy CT (DECT) and perfusion-CT (CTp) quantification of vascularisation pre- and day 1 post-ablation improves the assessment of residual disease versus complete ablation and predict for early recurrence in renal cancer.

Both DSCT (140kVSn/80kV, weight dependent contrast (Omnipaque 350) administration) and CTp (80-100kV, 40mL Omnipaque 350 IV) will be performed pre and d1 post ablation on a 3rd-generation Dual Source CT (Force, Siemens). A subgroup of 10 patients will undergo an additional CTp study on d14 post-ablation.
Follow up imaging will be performed at 3 and 9 months with DSCT using the same acquisition protocol as baseline DSCT.

Intervention Type
Other

Primary outcome measure

1. Sensitivity and specificity for residual and recurrent disease measured by i) morphological CT; ii) DECT iodine distribution; iii) CTp BF, BV and PS at baseline, 3-months, 9-months
2. Quantitative cut-offs that maximise sensitivity for residual and recurrent disease

Secondary outcome measures
1. Correlations between DECT and CTp parameters
2. Reproducibility of DECT and CTp parameters
3. Differences CTp measurements between d1 and d14

Overall study start date
19/09/2018

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Patients with T1 renal tumours referred for ablation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
48

Key exclusion criteria
1. Standard contraindications for contrast-enhanced CT including poor renal function (as per hospital protocol)
2. Previous contrast agent allergy

Date of first enrolment
01/06/2019

Date of final enrolment
31/12/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
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Sponsor information

Organisation
Guy's and St Thomas' and King's College London

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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
Royal College of Radiologists

Alternative Name(s)
The Royal College of Radiologists, RCR

Funding Body Type

Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
At the end of the study, the results will be presented at meetings and published in a medical journal. All information will be anonymous and at no time will it be possible for patients to be identified individually.

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof Vicky Goh (vicky.goh@kcl.ac.uk). Access would be to imaging protocol and anonymised results, on a case by case basis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No