

iSmaRT: Imaging small renal tumours

Submission date 30/08/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/10/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/05/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

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

Completion date

31/12/2025

Eligibility

Key inclusion criteria

Patients with T1 renal tumours referred for ablation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Guy's and St Thomas' NHS Foundation Trust

St Thomas' Hospital

Westminster Bridge Road,

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Sponsor information

Organisation

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

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

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