

# iSmaRT: Imaging small renal tumours

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

## Contact information

### Type(s)

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## **Additional identifiers**

**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?
<a href="#">HRA research summary</a>			28/06/2023	No	No