

# iSmaRT: Imaging small renal tumours

<b>Submission date</b> 30/08/2019	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/10/2019	<b>Overall study status</b> Ongoing	<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)

Public

### Contact name

Dr Adedayo Oke

### Contact details

Department of Clinical Imaging and Medical Physics  
Floor 4, Lambeth Wing  
St. Thomas' Hospital  
London  
United Kingdom  
SE1 7EH  
+44 (0)207 188 8381  
[adedayo.oke@gstt.nhs.uk](mailto:adedayo.oke@gstt.nhs.uk)

### Type(s)

Scientific

### Contact name

Prof Vicky Goh

### Contact details

King's College London  
Imaging Research Office  
Level 1 Lambeth Wing  
St Thomas' Hospital  
Westminster Bridge Rd

London  
United Kingdom  
SE1 7EH  
+44 (0)2071885550  
vicky.goh@kcl.ac.uk

**Type(s)**  
Scientific

**Contact name**  
Miss Muskaan Kaur

**Contact details**  
Becket House  
5th Floor  
1 Lambeth Palace Rd  
London  
United Kingdom  
SE1 7EU  
+44 207 188 7188  
Muskaan.kaur@gstt.nhs.uk

## **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

Westminster Bridge Road,

London

United Kingdom

SE1 7EH

## **Sponsor information**

**Organisation**

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

**Sponsor details**

16th Floor Tower Wing

Guy's Hospital

Great Maze Pond

London

England

United Kingdom

SE1 9RT

+44 (0)20 7188 7188 ext 56030

reza.razavi@kcl.ac.uk

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