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Virtual 3D modelling of the kidney anatomy to improve surgery planning for kidney cancer surgery

Submission date 20/04/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/04/2022	**Overall study status** Completed	
Last Edited 05/05/2022	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
A nephrectomy is the surgical removal of a kidney, performed to treat a number of kidney diseases including kidney cancer.
The goal of robotic assisted partial nephrectomy is to remove the tumour from the kidney whilst trying to preserve as much of the kidney as possible. Surgical planning is currently done using 2D CT images from which the surgeon has to mentally reconstruct the anatomy to try and understand the interrelationship of the tumour with other structures, this can be very difficult and is prone to human error. This can result in poor decision making, complications and long operating times. We propose to use virtual 3D models generated from the CT scan to improve surgical planning for complex tumours.

Who can participate?
Patients over 18 years, selected for robotic-assisted renal cancer surgery

What does the study involve?
If you were to take part in this research you would not receive any additional clinical tests or medical imaging scans. Any pre-operative scans (CT scan) that you have already undergone as part of the routine clinical care pathway will be assessed for suitability for personalised 3D model creation. If the scans are of sufficient quality, a 3D model will be generated. The 3D model will then be used, in addition to the original medical scans, at three stages to assist the surgeon: (1) with theatre planning (this is the plan for the actual operation, for example where the instrument ports will be positioned or which arteries will be selectively clamped); (2) with patient communications (medical scans are often difficult to interpret for the patient whereas the 3D model should be more intuitive); (3) with navigating the instruments during the operation and locating important structures.

What are the possible benefits and risks of participating?
The possible benefits of taking part in this study are;
1. Patients go home sooner due to higher-quality surgery and the reduced chance of complications, as a consequence of improved surgical planning.

2. Less likelihood of an unplanned conversion, which is when the surgeon has to abandon the minimally-invasive approach in favour of open surgery during the operation due to unforeseen anatomical challenges. This is reduced due to improved anatomical understanding.
3. Improved patient empowerment and improved consenting, resulting in better patient decision-making. This is due to the patient being able to see and understand their 3D anatomy.
4. Reduced procedure time with less exposure to anaesthetic. Operation times could be reduced because the surgeon now has a better understanding of the anatomy and a better preoperative plan.
This should lead to less time being spent searching for landmarks and key vessels.
Please note that these potential benefits have not yet been proven and we can't guarantee any direct treatment benefits from taking part in this study.
CT scans are already part of your routine care. If you take part in this study you will not undergo any additional CT scans. There is no risk associated with pregnancy and breastfeeding.

Where is the study run from?
Innersight Labs Ltd and King's College London (UK)

When is the study starting and how long is it expected to run for?
April 2021 to April 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Lorenz Berger, lorenz@innersightlabs.com

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295968

ClinicalTrials.gov number
NCT05109182

Secondary identifying numbers
IRAS 295968, CPMS 51658

Study information

Scientific Title
Virtual 3D modelling for improved surgical planning of robotic-assisted partial nephrectomy

Acronym
VISP

Study objectives
To establish whether surgical planning using virtual 3D modelling (Innersight 3D) improves the surgical outcomes and cost-effectiveness of complex robotic-assisted partial nephrectomy procedures.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/03/2022, Wales REC 1 (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 1792 606334; Wales.REC1@wales.nhs.uk), ref: 22/WA/0039

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
https://innersight-public.s3.amazonaws.com/295968_Patient_Information_Sheet_V1.1.pdf

Health condition(s) or problem(s) studied
Partial nephrectomy

Interventions
We propose to use virtual 3D models generated from the CT scan to improve surgical planning for complex kidney tumours.
The trial will recruit patients selected for robotic-assisted renal cancer surgery.
Patients will be randomised to either the control arm where only a CT scan will be used for surgical planning, which is the current gold-standard, or the intervention arm - where CT scan + 3D model will be used for surgical planning. The trial is planned to run for 18 months.

The UKCRC registered King's Clinical Trials Unit (KCTU) will provide 24/7 online 1:1 randomisation, Patients will then be documented within an Enrolment Log. Randomisation will happen once the patient has been termed eligible (following MDT). Randomisation will happen during the outpatient clinic, where the patient will be consulted about their upcoming partial nephrectomy operation. During this routine clinic appointment they will be consented and randomised.

Intervention Type
Procedure/Surgery

Primary outcome measure
Operating time measured using total console time (minutes) taken from patient notes recorded after surgery.

Secondary outcome measures
1. Hilum preparation time (minutes) measured using a timer recorded during surgery.
2. Tumor preparation time (minutes) measured using a timer recorded during surgery.
3. Tumor resection time (minutes) measured using a timer recorded during surgery.
4. Hilar clamping technique (global ischemia, selective ischemia, clampless, ice cooling) recorded during surgery.
5. Opened collecting system (yes, no) recorded during surgery.
6. Conversion to radical nephrectomy (yes/no) recorded during surgery.
7. Conversion to open surgery (yes/no) recorded during surgery.
8. Clamp time (minutes) measured using a timer recorded during surgery.
9. Experience level of surgeon measured using a questionnaire recorded after surgery.
10. Blood loss (ml) taken from patient notes recorded after surgery.
11. Total Operative time (mins) taken from patient notes recorded after surgery.
11. Length of stay (days) taken from patient notes recorded 4 weeks after surgery.
12. Margin status on histology (positive/negative) taken from patient notes recorded 4 weeks after surgery.
13. Pre/Post-operative eGFR (ml/min) taken from patient notes recorded at pre-operative assessment, 1 day after surgery, 4 weeks after surgery.
14. Pre/Post-operative creatinine (micromoles/L) taken from patient notes recorded at pre-operative assessment, 1 day after surgery, 4 weeks after surgery.
15. Pre/Post-operative Hemoglobin (g/dL) taken from patient notes recorded at pre-operative assessment, 1 day after surgery, 4 weeks after surgery.
16. Complications measured using the Clavien-Dindo Score recorded 4 weeks after surgery.

Overall study start date
01/04/2021

Completion date

01/04/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or above.
2. Agreement at Multidisciplinary team meeting that this patient could undergo robotic-assisted partial nephrectomy.
3. Willing and able to provide written informed consent.
4. RENAL score (tumour complexity) >= 8.
5. Received contrast enhanced abdominal preoperative CT scan.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
328

Key exclusion criteria
1. Do not consent for robotic assisted partial nephrectomy;
2. Chose to have treatment outside one of the NHS trial sites.
3. Participation in other clinical studies that would potentially confound this study;
4. Have a horseshoe, a solitary kidney or bilateral kidney tumours;
5. Lack of willingness to allow personal medical imaging data to be used for generating a 3D model;

Date of first enrolment
01/06/2022

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Guys Hospital
Guys Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
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Portsmouth Road
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Sponsor type
Industry

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Sponsor type
University/education

Website
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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Trial results will be published in a peer reviewed journal.

Intention to publish date
01/02/2024

Individual participant data (IPD) sharing plan
Any participant data will be anonymised for publication. The plan is to only publish summary outcome data of the trial - so that no individual participant data will need to be published.
The datasets generated during and/or analysed during the current study are not expected to be made available as Kings' College London (KCL) owns the Intellectual Property rights to the clinical outcomes data generated from the trial and no provisions have yet been made by KCL to publish this data, apart from summary statistics used for publication.

IPD sharing plan summary
Not expected to be made available

Study outputs

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