

# Image overlay for robot-assisted partial nephrectomy - a pilot study

<b>Submission date</b> 15/12/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/02/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 23/04/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Researchers are developing ways to improve robotic partial nephrectomies (removal of part of the kidney through keyhole surgery with the help of a robot controlled by the surgeon). One method would be to provide additional information to the surgeon by projecting the images from CT scans or MRI scans over the video images obtained during robotic surgery. This is not performed routinely at present because the pre-operative images cannot be accurately projected upon the video images obtained during the robotic surgery. The accuracy of the projection is affected by breathing motion, the pushing and pulling of the organs by the surgeon and due to the gas used during robotic surgery. The aim of this study is to investigate whether the use of computerised algorithms can calculate the position and change of shape required to accurately match the pre-operative CT or MRI scans to the live video images obtained during robotic surgery.

### Who can participate?

Patients over the age of 18, diagnosed with a small renal mass requiring robot-assisted laparoscopic partial nephrectomy

### What does the study involve?

The routine treatment plan will not change. However, the research would involve the following:

1. Video images from the laparoscope (available to the surgeon to perform the operation) will be recorded, anonymised and stored for later analysis.
2. The tracking information of the position of the various moving parts of the robot will be recorded.
3. Any pre-operative scans (MRI or CT) scans that have been undertaken will be overlaid on the video image. These images will be deformed using a computerised algorithm to account for the various deformation forces such as movement from breathing or pushing/pulling of organs by the surgeon.
4. There will be 1-2 additional personnel in the operating theatre to transfer the anonymised tracking and video image data from the Da Vinci Robot console.

Apart from recording the video images, using pre-operative scans and projecting them on the video screen, there will be no alteration in the care either during the time of recording or after completion of the operation.

What are the possible benefits and risks of participating?

The researchers do not anticipate any benefits to participants. If the research is successful, patients with a similar condition will benefit significantly because of the more detailed information that will be available to the operating surgeon.

The researchers do not anticipate any disadvantage or risks from taking part in this research. However, the true accuracy of the system in kidney surgery is not known since this system has only been used in people undergoing liver surgery previously. The accuracy of the system in people who undergo liver surgery was about 10 to 15 mm on average. The researchers anticipate better accuracy in kidneys since the kidney is more solid and less deformable than the liver. As there will be no interference with the video image that the surgeon will be using, The researchers do not anticipate any side effects of taking part.

Where is the study run from?

Royal Free Hospital (UK)

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

June 2017 to September 2025

Who is funding the study?

University College London (UK)

Who is the main contact?

Eddie Edwards

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## Contact information

### Type(s)

Scientific

### Contact name

Miss Maxine Tran

### Contact details

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## Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

## **Integrated Research Application System (IRAS)**

225688

### **Protocol serial number**

CPMS 35235, IRAS 225688

## **Study information**

### **Scientific Title**

Image guidance with image overlay for robot-assisted partial nephrectomy - a pilot study

### **Study objectives**

Pre-operative scan images can be used within a computerised algorithm to overlay pre-operative CT/MRI image onto intra-operative video images.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 07/06/2017, North East – Newcastle and North Tyneside (Room 001, Jarrow Business Centre, Rolling Mill Road, Jarrow, Tyne & Wear, NE32 3DT, UK; +44 (0)207 104 8282; nrescommittee.northeast-newcastleandnorthtyneside2@nhs.net), REC ref: 17/NE/0182

### **Study design**

Observational validation of investigation/therapeutic procedures

### **Primary study design**

Observational

### **Study type(s)**

Diagnostic

### **Health condition(s) or problem(s) studied**

Specialty: Cancer, Primary sub-specialty: Renal Cancer; Health Category: Cancer and neoplasms; Disease/Condition: Malignant neoplasms of urinary tract

### **Interventions**

The patient will be provided with an information sheet about the research. If the patient consents to being involved in the research, then they will be asked to sign the consent form, which allows the use of their pre-operative scan images, intra-operative video recording and also the retrieval of the tracking information of the instruments following the operation from the Da Vinci Robot. There will be no interference or change to the patients' usual clinical care. All data will be anonymised. The researchers will use a similar computerised algorithm that they have developed and used to overlay pre-operative images on live laparoscopic video images in patients undergoing diagnostic laparoscopy and laparoscopic liver resections. In this study they will overlay the pre-operative scan images onto the recorded intra-operative video images, and evaluate the error in the overlay (i.e. how far is the superimposed image from the live video image).

### **Intervention Type**

Other

### **Primary outcome(s)**

The accuracy of the overlay of pre-operative CT or MRI images onto live intra-operative laparoscopic images during robot-assisted laparoscopic partial nephrectomy; measured in mm as the distance between the aligned CT model and corresponding features in the endoscope view during the standard of care planned interventional surgery

### **Key secondary outcome(s)**

There are no secondary outcome measures

### **Completion date**

15/09/2025

## **Eligibility**

### **Key inclusion criteria**

1. Age >18 years
2. Diagnosed with small renal mass requiring robot assisted laparoscopic partial nephrectomy
3. Willing and able to provide written informed consent.

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

Does not meet inclusion criteria

### **Date of first enrolment**

18/10/2019

### **Date of final enrolment**

15/09/2025

## **Locations**

### **Countries of recruitment**

United Kingdom

England

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

## Sponsor information

**Organisation**  
University College London

**ROR**  
<https://ror.org/02jx3x895>

## Funder(s)

**Funder type**  
Research council

**Funder Name**  
Engineering and Physical Sciences Research Council; Grant Codes: EP/P012841/1

**Alternative Name(s)**  
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be included in the subsequent results publication

## IPD sharing plan summary

Other

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No