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

Submission date	Recruitment status	[ ] Prospectively registered
15/12/2020	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/02/2021	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/04/2025	Cancer	[X] 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
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
225688

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
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

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
07/06/2017

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

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
England

United Kingdom

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

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Sponsor type
University/education

Website

http://www.ucl.ac.uk/

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, EPSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2025

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?
HRA research summary			28/06/2023	No	No