Image-guided navigation during robot-assisted partial nephrectomy

Published: 30-05-2024
Last updated: 02-12-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON56771

Source
ToetsingOnline

Brief title
Navigated Partial Nephrectomy

Condition

- Renal and urinary tract neoplasms malignant and unspecified
- Renal disorders (excl nephropathies)
- Renal and urinary tract therapeutic procedures

Synonym
Renal cancer, Renal lesion

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: NKI-AvL

Intervention

Keyword: Image-guided surgery, Navigation, Partial nephrectomy, Renal lesions

Outcome measures

Primary outcome

The primary objective is to assess the ability to achieve preoperatively planned resection volumes by adding EM tracked navigation in RAPN, as minimizing the removal of healthy kidney tissue is challenging nowadays. A deviation within 35% between the planned and actual resection volumes is considered comparable and therefore deemed successful. The study is determined successful when at least 70% of the inclusions (i.e., 14 of 20 navigated procedures) reach a deviation below 35%.

During surgery, a 3D digital model shows the lesion alongside the resection plane defined by the surgeon. This visualization aids the surgeon in achieving the predetermined resection volume. After surgery, the actual resected volume is calculated based on a post-operative CT scans.

Secondary outcome

- To evaluate the time necessary to localize and remove the renal lesion by recording the time;

- To determine the clinical success of the procedure, marked by the number of negative resection margins;

- To evaluate the appearance of any technical issues during surgery related to the navigation setup;

- To evaluate the support for decisiveness during surgery compared to

conventional methods using a questionnaire for the surgeon.

Study description

Background summary

Robot-assisted partial nephrectomy (RAPN) is now the preferred option for treatable renal lesions due to its ability to preserve kidney function while effectively treating cancer. Despite RAPN's effectiveness, its surgical complexity and varied approach requirements pose challenges. Image-guided surgery applies pre-operative imaging for patient-specific intra-operative visualization of the kidney and lesion margins to support the surgeon during resection. However, adapting to surgery-induced deformations remains a challenge. An approach that is able to correct for organ movements during surgery might result in an optimal preservation rate of healthy kidney parenchyma and improved decisiveness for the surgeon during resection. On the long term, this might result in a larger shift from radical to partial nephrectomies, leading to patients with improved renal functions after lesion resection.

Study objective

The primary objective is to assess the ability to achieve preoperatively planned resection volumes by adding EM tracked navigation in RAPN, as minimizing the removal of healthy kidney tissue is challenging nowadays. A deviation within 35% between the planned and actual resection volumes is considered comparable and therefore deemed successful. Secondary objectives are the time for localizing and removing the renal lesion, the impact on surgical decisiveness, and the clinical and technical success of implementing the navigation setup.

Study design

Single center prospective feasibility study

Intervention

In the standard clinical workflow, diagnostic CT or MRI scans are acquired to visualize the renal lesion for removal. These images are used to create a 3D digital model to illustrate the lesion's relation to the kidney and surrounding anatomy. The surgeon reviews this model, validates the segmentation, and plans the resection volume. The surgical procedure proceeds according to standard protocols in a standard operational setting, with the addition of navigation tools. A sterile EM sensor is inserted through a separate 5mm trocar and

affixed to the kidney in proximity to the lesion in a region intended to be resected. Registration of the 3D model is conducted using an EM pointer or a tracked instrument, pointing to identifiable anatomical landmarks or structures on the kidney to validate accuracy. Both the digital model and the location of tracked instruments are displayed in real-time to the surgeon in the video console of the robot. The surgeon and researcher confirm the alignment visually through the integration of the model with tracked ultrasound imaging. Once verified, the surgeon conducts the resection according to own decision-making according to standard protocol while having navigation support. Data from tracking and ultrasound are recorded for further analysis after surgery. Post-operatively, the surgeon completes a questionnaire to evaluate the impact on decision-making compared to traditional surgical methods. A CT scan is used to calculate the resected volume and standard pathological assessment to confirm complete lesion removal.

Study burden and risks

The decision regarding tissue removal will be at the surgeon's discretion while having support of the conventional ultrasound and the navigation used for lesion identification. The study's measurements will not alter the planned surgical procedures, ensuring that patient treatment remains unaffected. A thorough risk analysis has indicated minimal to negligible risks, involving only an additional trocar of 5mm for EM sensor placement (which is negligible as normally there are five to six 10-15mm trocar placements to assist in RAPN in which one incision is enlarged for lesion removal) and a possible minor increase in surgery duration of at most 10 minutes .
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• Age >= 18 years
• Patient provides written informed consent form
• Patient is scheduled for robot-assisted partial nephrectomy

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Ferro-magnetic implants or other factors in the abdominal or thoracic area that could influence image quality
- Pacemaker or defibrillator

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-06-2024
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Kidney navigation setup
Registration:	No

Ethics review

Approved WMO Date:	30-05-2024
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86425.041.24