Image-guided navigation during robotic sentinel node removal

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26200

Source
NTR

Brief title
N21LND

Health condition

Prostate Cancer

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The percentage of successful image-guide assisted sentinel node procedures, in which success is defined as removing all the pre-operatively identified SN.Failure of using the navigation would be either not removing a target SN or removing per-operatively incorrectly identified target SN.

Secondary outcome

• SUS-Score
• Time to localization and removal of the sentinel node
• Surgery time
• LN size vs success rate

Study description

Background summary

Image-guided navigation based on pre-operative imaging can give the surgeon more insight into the location of the sentinel nodes in relation to other anatomical structures. The purpose of the study is to investigate the feasibility of image-guided navigation during robot-assisted surgery to treat cancer in the pelvic area. Ultimately, the application of navigation during robot-assisted sentinel node dissection could potentially improve the outcome of surgery for the patient.

Study objective

Image-guided navigation surgery allows the optimal use and full integration of pre-operative images during surgical procedure. This feasibility study investigates the potential of this technique in surgery of robot assisted sentinel node procedures. The hypothesis is that with navigation surgeons have a better insight in the anatomy of the patient and can more easily find the lymph nodes. This will improve the decision making, and can potentially also speed up the procedures.

Study design

Primary outcome: extracted SN will be validated ex-vivo.

Secondary outcomes: after surgery questionnaires will be given to the surgeons for feedback; the rest of the outcomes will be annotated during surgery.

Intervention

Use of an electromagnetic navigation system to improve insight and orientation during pelvic surgery.

Contacts

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Eligibility criteria

Inclusion criteria

• Scheduled for abdominal robotic sentinel node resection
• ≥ 18 years old
• Provided written ‘informed consent’
• Sentinel nodes should be fixed relative to retroperitoneal structures or major vessels

Exclusion criteria

• Metal hip implants/ implants in the pelvic area
• Pacemaker, defibrillator

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2021
Enrollment:	25
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	11-11-2021
Application type:	First submission

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
NTR-new	NL9865
Other	METC AvL : METC21.0657/N21LND

Study results

Summary results
N/A