Feasibility of in vivo image-guided navigation during robotic sentinel node removal

Published: 17-08-2021
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The purpose of the study is to test the feasibility of image-guided navigation during robot-assisted sentinel node dissection.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON54304

Source
ToetsingOnline

Brief title
Image-guided navigation during robotic sentinel node removal

Condition

- Other condition

Synonym
Sentinel node metastasis

Health condition

surgical and medical procedures - sentinel node dissection

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Image-guided navigation, Robot-assisted sentinel node removal, Sentinel node dissection

Outcome measures

Primary outcome

The main study endpoint is the feasibility of electromagnetic navigation during robot-assisted sentinel node dissection.

Electromagnetic navigation is considered feasible if in 75% of the sentinel node procedures the technology can be applied successfully.

In order to quantify the primary study parameter the percentage of successfully removed sentinel nodes will be taken into account. Success is defined when a sentinel node is correctly localized with navigation and perioperative validated with the gamma probe. Failure of using the navigation per sentinel node would be either not removing a target sentinel node or removing per-operatively incorrectly identified target sentinel node.

Secondary outcome

The first secondary study parameter is the time to localize and remove the sentinel node, together with the added time to surgery due to deploying navigation. The SUS-score will be used to evaluate the usability of the navigation within the surgery. The last study parameter will be the evaluation of the sentinel node size versus the success rate.

Study description

Background summary

Image-guided navigation surgery allows for full utilization of pre-operative imaging during open surgery, and has the potential of reducing both irradical resections and morbidity. Rapid extension of robot-assisted surgery has increased the need for robot-compliant image-guided techniques. This is the first feasibility study towards clinical implementation of the navigation setup into robot-assisted image-guided navigation surgery.

Study objective

The purpose of the study is to test the feasibility of image-guided navigation during robot-assisted sentinel node dissection.

Study design

Investigator initiated, prospective, non-randomized, feasibility study

Study burden and risks

The burden due to participation in the study is limited to an intra-operative CBCT scan, an US scan and prolonged surgery time (about 15 minutes for the CBCT or 5 minutes for the US). Only for the first 25 patients, due to the CBCT scan the patient will be exposed to some radiation (4 mSv). The risks associated with the extended operation time are considered limited, taking into account the duration of the operation.

No extra visits or interventions are associated with inclusion in the study. The surgical intervention will not be different from a routine robot-assisted sentinel node dissection.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Scheduled for abdominal robotic sentinel node resection
- >= 18 years old
- Provided written *informed consent*
- SN 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 invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-03-2022
Enrollment:	55
Type:	Actual

Medical products/devices used

Generic name:	Image-guided navigation setup
Registration:	No

Ethics review

Approved WMO Date:	17-08-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	17-08-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-04-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-03-2025
Application type:	Amendment
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	NL77462.031.21