Feasibility of in vivo image-guided navigation during a robot-assisted prostatectomy

Published: 17-03-2021
Last updated: 21-09-2024

To test the feasibility of image-guided navigation during robot-assisted prostatectomy

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Male genital tract therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON54359

Source
ToetsingOnline

Brief title
Image-guided navigation during robot-assisted prostatectomy

Condition

- Male genital tract therapeutic procedures

Synonym
Prostate cancer

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, Positive resection margins, Prostate cancer, Robot-assisted prostatectomy

Outcome measures

Primary outcome

The main study endpoint is the feasibility of electromagnetic navigation during RARP. Electromagnetic navigation is considered feasible if in 85% of patients the technology can be applied successfully.

A successful procedure includes: 1) successful placement of the EM sensors in the prostate and 2) accurate registration between the pre-operative 3D model of the patient and intra-operative situation. The registration is considered accurate if the mean target registration error is 1.0 cm or less. For assessing the accuracy of the registrations a set of independent positions of pre-defined anatomical structures and surfaces is used.

Secondary outcome

The first secondary study parameter is the added time to surgery due to deploying navigation. The second secondary study parameter is the accuracy of the different registration methods.

Study description

Background summary

Incomplete tumor resection or positive surgical margins are observed in up to 29% of specimens during histopathological evaluation of the specimens of patients treated with robot-assisted radical prostatectomy (RARP). Positive resection margins are associated with biochemical recurrence of the disease and require additional treatment post-surgery. Image-guided navigation, using

pre-operative imaging, can help the surgeon with recognizing the border of the prostate and the tumor thereby avoiding incomplete resection and positive resection margins. This could lead to improved surgical outcomes.

Study objective

To test the feasibility of image-guided navigation during robot-assisted prostatectomy

Study design

Investigator initiated, prospective, non-randomized, feasibility study

Study burden and risks

The burden due to participation in the study are limited to a prolonged surgery time (10-15 minutes). Risks related to the prolonged surgery time are considered limited taking in consideration the duration of the surgery.
No extra visits or interventions are associated with inclusion in the study.
The surgical intervention will not be different from a routine robot-assisted radical prostatectomy.

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

- >= 18 years old
- Scheduled for robot-assisted radical prostatectomy
- Biopsy-proven prostate carcinoma
- Available pre-operative MRI of sufficient quality for making the 3D model
- Written and signed informed consent

Exclusion criteria

- Allergic reaction to contrast agents in the past
- Metal implants in the pelvic area
- Defibrillator or pacemaker implant

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):	11-01-2023

Enrollment:	36
Type:	Actual

Medical products/devices used

Generic name:	Image-guided navigation setup
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	17-03-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	17-01-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-03-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	15-08-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL76713.031.21