Resect SAFE study: providing a reliable impression of the positive surgical margin in patients undergoing robot assisted radical prostatectomy for prostate cancer

Published: 08-02-2024
Last updated: 02-12-2024

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

Summary

ID

NL-OMON56573

Source
ToetsingOnline

Brief title
Resect SAFE study

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: Prostaatkanker Netwerk Nederland

Intervention

Keyword: Positive surgical margin, Prostate cancer, Robot assisted radical prostatectomy

Outcome measures

Primary outcome

The count of positive surgical margins among patients undergoing RARP for

prostate cancer, wherein exision of abundant tissue was conducted during the

RARP procedure.

Secondary outcome

- To evaluate the incidence of complications (rectal injury and postoperative

bleeding) among patients who have undergone the Resect SAFE procedure.

- To determine the rate of biochemical recurrence (at 6 months and 1 year)

within the cohort of patients subjected to the Resect SAFE procedure

Study description

Background summary

In Europe, prostate cancer is the most prevalent malignancy among males aged 50 and above. Robot-assisted radical prostatectomy (RARP) represents the favored therapeutic approach for patients with localized prostate cancer. The primary objective of this procedure is the complete excision of all prostate cancer tissue. When evaluating the outcomes of this surgical intervention, a persistent high positive surgical margin (PSM) rate becomes evident. Across various studies, approximately 30% of patients undergoing RARP exhibit a positive surgical margin in the pathology specimen. Furthermore, diverse investigations demonstrate that patients with a positive surgical margin experience inferior oncological outcomes, as indicated by postoperative biochemical recurrence.

Consequently, the imperative arises to mitigate the incidence of positive surgical margins. Our supposition is that achieving this objective is attainable through surgical refinement of the procedure, involving the excision of abundant tissue at locations where, based on the positioning of the prostatic tumor, a positive surgical margin is anticipated. The occurrence of a positive surgical margin is expected in regions characterized by a higher number of prostate biopsies yielding cancer diagnosis and/or at sites where the prostatic tumor is discernible on the diagnostic preoperative magnetic resonance imaging (MRI) scan. The resection of abundant tissue surrounding the prostate can potentially lead to the removal of a greater extent of prostate cancer tissue, consequently contributing to a reduced positive surgical margin rate.

Study objective

The primary objective of this study is to reduce the incidence of positive surgical margins in patients undergoing RARP by conducting an intraoperative excision of abundant peri-prostatic tissue.

Secondary endpoints include the number of complications arising from the excision of abundant peri-prostatic tissue and the percentage of biochemical recurrence at 6 months and 1 year.

Study design

It is a prospective monocenter observational cohort study, with the inclusion of patients undergoing RARP at the Antoni van Leeuwenhoek Hospital. The study duration extends for a period of 12 months.

Intervention

During the prostatectomy, subsequent to the prostate removal and achieving satisfactory hemostasis, abundant tissue is excised on the non-nerve-sparing side(s) surrounding the area previously occupied by the prostate, as well as at the location of the neurovascular bundle.

Study burden and risks

Very low risk (<<5%) of postoperative bleeding or injury to the rectum.

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

Undergoing a non-nerve-sparing robot assisted laparoscopic radical prostatectomy (unilateral or bilateral non-nerve-sparing).
Any value of prostate-specific antigen (PSA).
Any grade from the International Society of Urological Pathology (ISUP).
Any tumor (T) stage on the magnetic resonance imaging (MRI) scan.

Exclusion criteria

Molecular Imaging (MI), specifically on PSMA-PET, a lymph node (N) stage 1
Salvage prostatectomy
NeuroSAFE procedure.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-04-2024
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	08-02-2024
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	NL85258.041.23