A prospective observational multicentre study concerning non-technical skills in robot assisted radical cystectomy versus open radical cystectomy.

No registrations found.

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

Summary

ID

NL-OMON24794

Source NTR

Brief title NTS-RARC

Health condition

urothelial cell carcinoma of the bladder

Sponsors and support

Primary sponsor: Investigator initiated study **Source(s) of monetary or material Support:** None

Intervention

Outcome measures

Primary outcome

The following outcomes will be reported.

1 - A prospective observational multicentre study concerning non-technical skills in ... 13-05-2025

Non-technical skills will be observed using five different methods.

1. NOTSS: Non-Technical Skills for Surgeons16

The focus of the NOTSS assessment method lies on the following aspects of NTS: - Situation Awareness: Developing and maintaining a dynamic awareness of the situation in operating theatre based on assembling data from the environment, understanding what they mean, and thinking ahead about what may happen next.

- Decision Making: Skills for diagnosing the situation and reaching a judgement in order to choose an appropriate course of action.

- Communication and Teamwork: Skills for working in a team context to ensure that the team has an acceptable shared overview of the situation and can complete tasks effectively.

- Leadership: Leading the team and providing direction, demonstrating high standards of clinical practice and care, and being considerate about the needs of individual team members.

2. Oxford NOTECHS II: A Modified Theatre Team Non-Technical Skills Scoring System11,12 The focus of the NOTECHS II assessment method lies on the following aspects of NTS:

- leadership and management
- teamwork and co-operation
- problem-solving and decision-making
- situation awareness

3. OTAS: Observational Teamwork Assessment for Surgery20

The focus of the OTAS assessment method lies on the following aspects of NTS:

- communication
- coordination
- cooperation and back up behaviour
- leadership
- team monitoring and situational awareness

4. ICARS: non-technical skills evaluation in robotic surgery17

The focus of the ICARS assessment method lies on the following aspects of NTS:

- checklist and equipment

- interpersonal skills (communication and team skills & leadership)
- cognitive skills (decision-making & situational awareness)
- resource skills (stress and distractors)

5. Human factors analysis21

Human factors analysis consists of 4 levels of system failure: unsafe acts, preconditions for unsafe acts, unsafe supervision, and organizational influences.

Technical skills in RARC will be analysed using two different methods:

5. GEARS: Global Evaluative Assessment of Robotic Skill7.

The focus of the GEARS assessment method lies on general robot surgical principals, i.e. Depth perception, bimanual dexterity, efficiency, force sensitivity, autonomy, and robotic control

6. GERT: Generic Error Rating Tool5.

The focus of the GERT assessment method lies on the capture and analysis of technical errors

and resulting events during laparoscopic procedures.

Secondary outcome

Age, WHO performance status, Charlson comorbidity index, neoadjuvant chemotherapy, prior local treatment, prior radiation therapy in the surgical field, diagnosis, prior abdominal and/or pelvic surgery, the indication of surgery, per-operative complications, postoperative complications according to the Clavien-Dindo system22, length of hospital stay, ICU stay, blood loss, PREMS, PROMS, method of surgery, and oncological outcome (Surgical margins and number of resected lymph nodes, and pathology results) will be registered prospectively. Patient follow-up will be at least 30 days.

Study description

Background summary

This study uses a structured approach to non-technical skills (NTS) analysis using extracorporeal videos of both open radical cystectomy and robot assisted radical cystectomy surgeries in order to obtain detailed data on NTS during open and minimal invasive surgery. The strength of this study includes the use of high-quality and detailed analysis of leadership, decision making, and communication during surgery by combining multiple NTS assessment tools used by trained observers.

Study objective

- The introduction of Robot assisted surgery leads to an initial decay in NTS behaviour during the learning curve of the team.

- In experienced robot assisted surgery teams NTS behaviour is more explicitly expressed compared to experienced open surgery teams.

- The introduction of Robot assisted surgery leads to the development of different forms of NTS behaviour compared to open surgery.

Study design

The inclusion will be from January 2021 until August 2022 in both hospitals simultaneously (figure 1). The video collection will start once the first patient is included and will continue until the last patient has had his surgery. Follow-up data collection will start in February of 2021 and will continue until December of 2022. Data analysis will start in January 2022.

Intervention

An Open Radical Cystectomy (control) or Robot Assisted Radical Cystectomy (Intervention)

Contacts

Public Catharina hospital Eindhoven Alexander Beulens

0031402397040 **Scientific** Catharina hospital Eindhoven Alexander Beulens

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Eligibility criteria

Inclusion criteria

Patients who will undergo either an Open Radical Cystectomy (ORC) or Robot Assisted Radical Cystectomy (RARC) in Catharina Hospital Eindhoven or Antoni van Leeuwenhoek hospital are eligible for this study. The choice of treatment is at the discretion of the patient and the surgeon.

For study inclusion, the following criteria must be met:

- Patients must be at least 18 years of age.
- patients must be able to understand and sign an informed consent.

- Patients who will undergo either an Open Radical Cystectomy (ORC) or Robot Assisted Radical Cystectomy (RARC) in Catharina Hospital Eindhoven or Antoni van Leeuwenhoek hospital.

- indication for the radical cystectomy must be urothelial cell carcinoma of the bladder.

- Informed consent of the patient to gather data and perform observations during surgery.

Exclusion criteria

No exclusion criteria will be used for this study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	270
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion	
Date:	17-04-2020
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	NL8537
Other	MEC-U : W19.048

Study results