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

Gepubliceerd: 17-04-2020 Laatst bijgewerkt: 18-08-2022

- 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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24794

Bron
NTR

Verkorte titel
NTS-RARC

Aandoening

urothelial cell carcinoma of the bladder

Ondersteuning

Primaire sponsor: Investigator initiated study
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The following outcomes will be reported.

Non-technical skills will be observed using five different methods.
1. NOTSS: Non-Technical Skills for Surgeons[16]
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 System[11,12]
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 Surgery[20]
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 surgery[17]
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 analysis[21]
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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

- 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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Catharina hospital Eindhoven
Alexander Beulens

0031402397040

Wetenschappelijk

Catharina hospital Eindhoven
Alexander Beulens

0031402397040

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No exclusion criteria will be used for this study.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	270
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	17-04-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8537
Ander register	MEC-U : W19.048

Resultaten