RAdicale Cystectomy Evaluation. Comparative Effectiveness Study of Open versus Robot Assisted Laparoscopic Surgery

Gepubliceerd: 14-08-2015 Laatst bijgewerkt: 18-08-2022

Objective: To study the (cost-)effectiveness of robotic compared to open cystectomy in patients with bladder cancer

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

Samenvatting

ID

NL-OMON24266

Bron
NTR

Verkorte titel
RACE

Aandoening

1.bladder cancer
2. (cost)-effectiveness
3. cystectomy
4. robot
5. surgery
6. complication
7. quality of life

Ondersteuning

Primaire sponsor: Rijnstate Hospital
Overige ondersteuning: ZONMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Complications, i.e. the 90 days overall complication rate according to the Clavien-Dindo classification.

Toelichting onderzoek

Achtergrond van het onderzoek

OBJECTIVE/RESEARCH QUESTION:
To study the (cost-)effectiveness of robotic compared to open cystectomy in patients with bladder cancer.

STUDY DESIGN
An open multi-centre comparative effectiveness study in 338 patients with bladder cancer in 23 centers (11
RARC, 12 ORC) in the Netherlands. Follow-up will be 12 months.

STUDY POPULATION
Patients selected for a radical cystectomy according to current guidelines.

TIME SCHEDULE
December 2015 – December 2019, 48 months

Doel van het onderzoek

Objective: To study the (cost-)effectiveness of robotic compared to open cystectomy in patients with bladder cancer

Onderzoeksopzet

Perioperative morbidity and mortality are evaluated using the modified Clavien grading system for complications by prospectively recording intraoperative and postoperative complications until discharge and by patient questionnaires/interviews during the post-

discharge period until 90 days after surgery.

HRQL outcomes are measured at baseline and postoperatively at 1,3, 6 and 12 months using the Functional Assessment of Cancer Therapy–Vanderbilt Cystectomy Index (FACT- BI-Cys) , the Bladder Cancer Index (BCI), and the EQ-5D questionnaires.

Pathological data is obtained from pathology reports after surgery with particular emphasis on surgical margin status, total number of lymph nodes removed and their involvement with cancer, as well as pathological stage of the tumour. A standardised form will be used to collect all information pertaining to specimen processing and staging by the participating institutions.

Perioperative measures, e.g. blood transfusion rates, intraoperative fluid requirements, operative time, postoperative length of hospital stay and analgesic requirement, are prospectively recorded during surgery and the postoperative hospital stay using anaesthesia, operative, nursing and inpatient medical records by a research nurse. Operating time is defined as the skin to skin operating time in minutes not including anaesthetic preparations as these might differ between the participating hospitals.

All patients will be instructed to record their symptoms during the study period. Resource use will be assessed using two questionnaires. The iMCQ will be used to assess medical consumption such as hospital visits, medication use and domestic help. The iPCQ will be used to measure absence from work due to illness. Both questionnaires will be completed at the start of the study before the treatment and every 3 months afterwards. The total follow-up will be 12 months.

Onderzoeksproduct en/of interventie

Robot assisted radical cystectomy (RARC) will be compared with open radical cystectomy (ORC)

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Patients with non-metastatic muscle-invasive (cT2-T4a) and uncontrolled or highrisk non Muscle-invasive bladder cancer (pTa-pT1)

• Age >=18

• Able to fill in questionnaires

• Signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Extensive previous abdominal surgery

• Abdominal irradiation

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd

Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2015
Aantal proefpersonen:	338
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-08-2015
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	NL5214
NTR-old	NTR5362
Ander register	ZonMw; CMO regio Arnhem-Nijmegen : 843002602; 2015-1942

Resultaten