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

No registrations found.

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

Summary

ID

NL-OMON24266

Source
NTR

Brief title
RACE

Health condition

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

Sponsors and support

Primary sponsor: Rijnstate Hospital
Source(s) of monetary or material Support: ZONMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

HRQOL, time to return to normal activity, operating time, hospital and intensive care stay, blood loss, transfusion parameters, costs, pathology results

Study description

Background summary

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

Study objective

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

Study design

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.

Intervention

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

Contacts

Public
wagnerlaan 55

C.J. Wijburg
Arnhem 6815 AD

The Netherlands
tel +31(0)88-005 6082
Scientific
wagnerlaan 55

C.J. Wijburg
Arnhem 6815 AD
The Netherlands
tel +31(0)88-005 6082

Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• Extensive previous abdominal surgery

• Abdominal irradiation

Study design

Design

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

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2015
Enrollment:	338
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-08-2015
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	NL5214
NTR-old	NTR5362
Other	ZonMw; CMO regio Arnhem-Nijmegen : 843002602; 2015-1942

Study results