The RACC trial -Robot-assisted Approach to Cervical Cancer. A multi-centre open-label randomised non-inferiority trial of robotassisted laparoscopic surgery versus laparotomy in women with early stage cervical cancer.

Published: 03-11-2020
Last updated: 19-10-2024

We aim to demonstrate that robot-assisted laparoscopic radical hysterectomy is non-inferior to conventional laparotomy in recurrence free survival of patients with early stage cervical cancer (stage 1B1, 1B2 and 2A1).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON49363

Source
ToetsingOnline

Brief title
RACC-trial

Condition

- Reproductive neoplasms female malignant and unspecified
- Cervix disorders (excl infections and inflammations)
- Obstetric and gynaecological therapeutic procedures

Synonym
cervical cancer, cervical carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Karolinska University Hospital
Source(s) of monetary or material Support: Karolinska University Hospital

Intervention

Keyword: Disease free survival, Early stage cervical cancer, Robot-assisted laparoscopic surgery

Outcome measures

Primary outcome

We expect to include 200 patients during the 3-year recruitment phase. In these patients, we expect a recurrence free survival of 88% with no difference between the laparotomy and robot assisted groups based on the Dutch cervical cancer treatment analysis.

For the international study population, as mentioned in the protocol the RFS is 85% The hypothesis is that there is no difference between the two groups with a non inferiority threshold of 7.5% In summary: With a recurrence free survival of 85%, with a power of 80% and an alpha of 5%, a difference of> 7.5% can be excluded.

Secondary outcome

• Overall survival

• Health related quality of life including lymphoedema, bladder and sexual dysfunction

• Intraoperative complications

• Postoperative complications

• Diagnostic accuracy of the pelvic sentinel lymph node concept

Secondary outcomes are expected to be a shorter hospital stay and less

complications reflected in better QoL scores for the RALS-treated group.

Study description

Background summary

Cervical cancer is a relatively rare tumour with little under 700 new cases each year in the Netherlands. Roughly half of those patients are considered operable and have a good prognosis with a disease free 5-year survival of 85-98% depending on among other things, histology and operative radicality . The standard treatment for these patients is surgical removal of the uterus (radical hysterectomy) (including parametrial resection with ureteric and bladder mobilization and a pelvic lymphadenectomy). This type of surgery is associated with complication risks and increased morbidity including slower postoperative recovery, voiding problems and swelling (lymphedema). Reduction of morbidity and improvement of recovery have been the main focus to improve patient care, while concurrently maintaining good oncological outcome.
Robot assisted laparoscopic surgery (RALS) has strongly improved the standard of care with the advantage of shorter hospital stay and less postoperative complications.in several Dutch cancer centres, including Erasmus MC UMCU, Radboud MC and MUMC. Data from the Dutch cancer registration (supplemented with an extensive treatment dataset) shows there is no difference in survival or recurrence between surgical methods (open conventional surgery or RALS). However, results from an international randomized trial (LACC-trail) that compared mainly conventional (not robot assisted) laparoscopic surgery and laparotomic surgery (initiated 2007) shows that patients subjected to conventional laparoscopic surgery had an increased risk of recurrence. This difference was not observed in, among other analysis, Sweden, Denmark or the Netherlands with robot-assisted laparoscopic surgery. This has caused an intense debate, whether the results from the LACC trial represents all of the western world and Europe in specific. Therefore, the multi-centre RACC trial was initiated by the Karolinska Hospital Stockholm
In this project, we will perform a randomized trial to establish the oncological safety of current minimally invasive practice (RALS) in the Netherlands.

Study objective

We aim to demonstrate that robot-assisted laparoscopic radical hysterectomy is non-inferior to conventional laparotomy in recurrence free survival of patients with early stage cervical cancer (stage 1B1, 1B2 and 2A1).

Study design

Randomised controlled non-inferiority trial.
We will randomize women diagnosed with squamous cell or adeno carcinoma of the cervix indicated for radical hysterectomy 1:1 to either robot assisted or laparotomic surgery. Quality of life (QoL) analyses will be performed with questionnaires. After standard 5-year follow-up, we will compare recurrence free survival , quality of life measurements, as well as cost-effectiveness (average length of hospitalization and complications)
This project proposal entails the Dutch multi-centre participation of the RACC trial (RACC-trial the Netherlands)

Intervention

Robot-assisted laparoscopic radical hysterectomy and pelvic lymphadenctomy versus radical hysterectomy and pelvic lymphadenectomy by laparotomy

Study burden and risks

There is no additional risk and minimal burden associated with trial participation since both treatments are standard clinical practice. The additional burden consists of the time spend to fill out the questionnaires

Contacts

Public
Karolinska University Hospital

Eugeniavägen 3
Solna, Stockholm 171 76
SE
Scientific
Karolinska University Hospital

Eugeniavägen 3
Solna, Stockholm 171 76
SE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Histologically confirmed primary adenocarcinoma, squamous cell carcinoma or adenosquamous
carcinoma of the uterine cervix;
• Women with histologically confirmed FIGO stage IB (IB3 excluded) and IIA1 disease. It is at the discretion of local principal investigators to decide if tumours fulfilling the SHAPE-criteria should be considered an exclusion criterion (pending revisions of national and international guideline recommendations).
• Women undergoing either a Type B or C radical hysterectomy according to Querleu
Morrow classification
• ECOG Performance Status of 0, 1 or 2
• Patient must be suitable for surgery.
• Patients who have signed an approved Informed Consent
• Age> 18 years

Exclusion criteria

• Any histology other than adenocarcinoma, squamous cell carcinoma or adeno-squamous
carcinoma of the uterine cervix
• Tumor size greater than 4 cm, estimated by either magnetic resonance imaging (MRI) or
clinical examination
• FIGO stage II-IV (except IIA1). It is at the discretion of local principal investigators to decide if tumours fulfilling the SHAPE-criteria should be considered an exclusion criterion (pending revisions of national and

international guideline recommendations).
• Women with a history of pelvic or abdominal radiotherapy
• Women who are pregnant
• Women with contraindications to surgery
• Women with evidence of metastatic disease by conventional imaging studies, enlarged
pelvic or aortic lymph nodes > 2cm; or histologically positive lymph nodes
• Serious concomitant systemic disorders incompatible with surgery or study (at the
discretion of the investigator)
• Women unable to withstand prolonged lithotomy and steep Trendelenburg position
• Women with secondary invasive neoplasm in the last 5 years (except non-melanoma
skin cancer, breast cancer T1 N0 M0 grade 1 or 2 without any signs of recurrence or
activity)
• Women with iodine allergy cannot be part of the sentinel node part of the trial but are
allowed randomisation as to the primary outcome

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-01-2021
Enrollment:	200
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	03-11-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-11-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	10-10-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT03719547

Register	ID
CCMO	NL72104.078.20