Robot-assisted Approach to Cervical Cancer

Robot-assisted surgery versus laparotomy in women with early cervical cancer

Dear Investigator,

Thank you for being interested in participating in the RACC trial.

In order to evaluate the feasibility of your site for participation some information regarding surgical quality and resources needs to be disclosed.

Please read, complete and sign the following documents together with the required reports and send it by email to: *sahar.salehi@sll.se*

According to the study protocol the following criteria are to be fulfilled by centers considered for participation in the trial.

- Established robotic surgery unit for at least 3 years
- At least 10 radical hysterectomies for early stage cervical cancer per year in the unit
- Minimum of 20 radical upfront debulking surgeries per year for advanced ovarian cancer
- Intensive care unit available
- Ability to perform ultrastaging of lymph nodes
- Ability to review all specimens by a reference pathologist

The Trial Steering Committee requires following information from each institution before initiation, data is required for the last 24 months:

- 10 anonymized surgical reports of patients that have undergone radical hysterectomy for cervical cancer
- 10 anonymized surgical reports of patients operated upfront with radical debulking surgery for advanced ovarian cancer
- For each patient, the surgical report is accompanied by corresponding anonymized pathological report.
- Attached to each surgical report, operation time in minutes, per-operative bleeding in mL and 30-day postoperative complications according to Clavien Dindo classification must be stated.

Information on study site

Hospital name	
Department	
Street	
Zip code/City/Country	
Principal investigator	
Participating surgeons	
Research coordinators and study nurses/assistants	
Telephone number **Investigator** **Research Coordinator**	
Fax **Investigator** **Research Coordinator**	
Email **Investigator** **Research Coordinator**	

Facilities/Technique/Resources

Centralized care of cervical cancer patients	☐ yes	☐ no
Intensive Care unit available	☐ yes	☐ no
Access to transfusions	☐ yes	☐ no
Access to medical and radiation oncology	☐ yes	☐ no
Capacity to perform surgery within 4 weeks of enrollment	☐ yes	☐ no
Close documentation within 4 weeks after each planned visit according to protocol can be assured	☐ yes	☐ no

Specify available resources for documentation:

Name of responsible person for documentation:

Available resources for monitoring of data:

Name of responsible person for monitoring of data:

Agreement to use an e-CRF	☐ yes	☐ no
Agreement to register all patients eligible with early stage cervical cancer into a screening log	☐ yes	☐ no
Agreement to be visited and audited by RACC Trial Steering committee members during the recruitment period of the study	☐ yes	☐ no

Surgery and histopathology

Radical Hysterectomies with lymph node dissection _____ per year

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer patients with upfront surgery _____ per year

Radical hysterectomy with lymph node dissection

Year 2019: _____ pts operated,
_____ pts with sentinel node biopsy
Proportion of operations in robot ≈_____ %

Year 2020: _____ pts operated,
_____ pts with sentinel node biopsy
Proportion of operations in robot ≈_____ %

Radical Upfront Debulking Surgery in FIGO Stage III-IV Ovarian or fallopian tube cancer patients

Year 2019: _____ pts operated,
_____ complete resections,
Proportion of complete tumor resection achieved ≈_____ %

Year 2020: _____ pts operated,
_____ complete resections,
Proportion of complete tumor resection achieved ≈_____ %

Ability to perform ultrastaging of lymph nodes and possibly many lymph nodes ☐ yes ☐ no

Access to a gynaecologic reference pathologist ☐ yes ☐ no

Ability to close documentation on pathology report within 6 weeks after surgery ☐ yes ☐ no

Interest in participating in the sentinel node part of the RACC trial	☐ yes	☐ no
If yes, interested in adherence to the RACC-trial protocol (see protocol 5.4) and accepting on-site training from the Trial steering committee	☐ yes	☐ no
If yes, interested but with other/own algorithm	☐ yes	☐ no
If yes, please provide detailed description of your algorithm on a separate document and attach to the Site Quality Assessment Form		

Adjuvant Treatment

Standard adjuvant treatment for patients fulfilling critera after primary surgery for early stage Cervical cancer is Extern radiotherapy, standard dose 45 Gy with weekly Cisplatin 40 mg/m^2	☐ yes	☐ no
If no, please specify in a separate word document the standard adjuvant treatment		
Do you use Sedlis critera to select patients for adjuvant treatment?	☐ yes	☐ no
If no, please specify in a separate word document how you select patients actual for adjuvant treatment and attach the document.		
Please provide details on the proportion of operated patients with early stage cervical cancer subjected to adjuvant treatment during the last 24 months.	_____%	

The principal investigator of each centre is responsible that all the above criteria are met by the operating team and can assure that all required information is available and emailed after scanning as PDF to the study group at the following address:

sahar.salehi@sll.se

Registration of your information in the Site identification and quality assessment form of the RACC trial will result in Karolinska University Hospital processing your personal data. Acceptance is a prerequisite and your signature below a confirmation of acceptance. For more information about personal data, contact the data protection officer *(Dataskyddsombud.karolinska@sll.se).*

Date and Signature of Prinicpal Investigator

Thank you very much for your interest in this study!