Patient information and consent form

Randomised trial comparing open versus robot-assisted laparoscopic surgery
in early-stage cervical cancer

Background and purpose

Treatment of patients with early-stage cervical cancer consists of surgery with aim of resection of the uterine cervix including adjacent tissue (radical hysterectomy) and lymphnodes in the pelvis. Radiation and chemotherapy after surgery might also be necessary.

Previously, most patients with cervical cancer had open surgery where the abdomen is accessed by a large incision. Nowadays, minimally invasive surgery with the help of a so-called robot is an established method by which the majority of patients with early-stage cervical cancer are treated in the Nordic countries. With this surgical method, there are only a few, one centimeter long incisions on the abdomen. Robot-assisted laparoscopic surgery is also used for the treatment of many other cancer diagnoses as well (for example: endometrial cancer, cancer in the urinary bladder and prostate). The advantages of robot-assisted laparoscopic surgery is foremost shorter length of hospital stay, minimal incisions on the abdomen and faster recovery after surgery.

Data from our Swedish and Danish quality registries do not show any difference in survival or recurrence depending on which surgical method is chosen (open or robot-assisted laparoscopic surgery). However, results from an international randomised trial between conventional laparoscopic surgery (not robot-assisted laparoscopic surgery) that started in 2007 shows that patients subjected to conventional laparoscopic surgery (not robot-assisted laparoscopic surgery) had an increased risk of recurrence.
In the Nordic countries where robot-assisted laparoscopic surgery is used we have not observed this difference.

For this reason, we have started a randomised trial with aim to establish which surgical method gives the best outcomes for the patients in terms of quality of life, complications and recovery and foremost if there is a difference in recurrence depending on surgical method. This will help us understand which method that serves the patient best.

The trial is initiated by surgical gynecologic oncologists at Karolinska University Hospital but will include patients from all Nordic countries. The aim is to recruit 800 patients in the Nordic countries and probably also from other countries.

Request for participation

Since you have been diagnosed with cervical cancer we ask if you want to participate.

How is the study conducted?

If you choose to participate the following will take place:

Randomisation to surgical method:

- You will be randomised to either open surgery or robot-assisted laparoscopic surgery. ***There is no difference in the surgical procedure that is performed, only which surgical method used.***
  The randomisation is performed at the Center for clinical cancer studies (CTO/CKC) at Karolinska University Hospital and your treating physician cannot influence which method of surgery you will be randomised to.

- You will be informed of the treatment and treated according to routine practice regardless of which method of surgery you will be randomised to.

- We will ask you to answer quality of life questionnaires at different time points (before randomisation, 1 month, 6 months, 1 year, 2 years and 5 years after surgery). The questionnaires will take 15 to 20 minutes to complete each time.

- The follow-up after surgery will be according to routine practice every 6 months apart from one extra out-patient visit one month after surgery

- Apart from routine blood samples additional blood will be collected as part of the study which are stored in a biobank. These samples will be collected at time of the already scheduled out-patient visits at 1 month, 1 year and 2 years after surgery. Genetic (DNA) analyses of the blood-samples will be performed with aim of finding markers for recurrence and prognosis. A regular pap-smear from the uterine cervix will also be collected at time of surgery. We will also make study specific analyses on material that has been collected for routine diagnostics. The study does not affect standard routine for handling samples, analyses or diagnostics of tissue. Standard blood samples will be discarded as per clinical routine.

Data and privacy management

Your personal data, i.e. data about you and your participation in the current study are recorded in a database. The personal data processed are those that are relevant for the study such as birth year, disease, surgical and possibly oncological treatment. Your information, responses and results will be treated so that unauthorized persons will not be able to access them. It is the Center for Clinical Cancer Studies (CTO / CKC) at Karolinska Universityhospital which is responsible for the database and all data in it is coded. Data and study-specific samples are stored for 10 years after completion of the study. Participation in the study is completely voluntary. This means that the disclosure of personal data is also voluntary. Personal data is only collected from you, your journal and the health care personnel responsible for the clinical trial.

A so-called monitor will have access to the data to perform quality control by comparing the data reported in the study with those contained in your patient record to ensure that the data in the study is correct and that patient safety is maintained. In the event of a regulatory inspection, your personal information can be submitted to the Medical Products Agency or the corresponding national or international supervisory authority. You can request, free of charge, once a year, information on how your personal data is processed (COUNTRY SPECIFIC). You can also request that incorrect data be corrected. Patient data is protected in accordance with the European Union (EU) General Data Protection Regulation (GDPR). For your personal information, confidentiality is governed by the NAME OF NATIONAL ACT/LAW.

Are there any risks?

To participate in the study does not confer added risks since both open and robot-assisted laparoscopic surgery are already performed as normal routine clinical practice. Information on specifics of surgery will be given by your treating physician.

Blood-samples: The study-specific blood-samples will be collected in the same way as routine blood-samples and does not add any risks. The amount of blood collected is equivalent to one table spoon at each time (20 mL).

Pap-smear: The extra pap-smear taken from the uterine cervix at time of surgery does not add any risks for you.

Are there any benefits?

To participate in the study does not give any personal benefits. The results of the study will contribute to better treatment of patients with the same disease as you in the future.

How will I be informed of the results of the study?

The results will be published in special literature after end of the study. The results from the analyses are coded and will not be published on an individual basis.

Insurance

Coordinating investigator in the country is to make sure proper insurance are in place for the participants.

Voluntary participation

To participate in research is always voluntary and you may at any time, without explanation discontinue your participation. If you choose to discontinue participation, no more data from you will be collected. Your treatment will not be affected in any way if you choose to discontinue your participation.

Please do not hesitate to contact us regarding any study specific questions. Contact information below:

NAME, title
Principal Investigator at SITE
Institution
Phone and/or email

NAME, title
Sub-Investigator/Study coordinator at SITE
Institution
Phone and/or email

Responsible for personal data protection at HOSPITAL
HOSPITAL switchboard phone nr, ask to speak to person responsible for data protection.
Alternatively email to: xxx@yyyy .

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Consent to participate in the "Randomised trial comparing open versus robot-assisted laparoscopic surgery in early-stage cervical cancer - RACC-trial "

- I have read the written information on "Randomised trial between open and robot-assisted laparoscopic surgery in early-stage cervical cancer - RACC-trial".
- I have had the opportunity to ask questions and have them answered
- I hereby give my consent to participate in the trial and know my participation is completely voluntary.
- I am fully aware that I at any time and without explanation, can withdraw my consent and end my participation without affecting my care
- I consent to have my personal data registered according to the information I have been given and that my collected data is stored and handled electronically by the study managers.
- I consent to that study managers, monitors and regulatory authorities access my patient record information that is relevant to the current study and future ethically approved studies.
- I consent to have my data matched to other national health registers for follow-up of treatment and the disease.

Date: .....

Signature: .....

Name in capitals: .....

Informing investigator's/doctor's signature

I hereby confirm that I have given both oral and written information about the described study and that a copy of the patient informed consent form has been handed out to the patient signing this consent form.

Signature	Name in capitals	Date
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