Sentinel node biopsy in Low- and Intermediae endometrial cancer Management: The SLIM-study

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1. To assess the feasibility of SLN identification in endometrial cancer.2. To examine in how many cases SLN biopsy provides results that will tailor adjuvant treatment3. To investigate if SLN biopsy in women with low- and intermediate-risk...

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

Summary

ID

NL-OMON41827

Source
ToetsingOnline

Brief title
SLIM study

Condition

- Reproductive neoplasms female malignant and unspecified
- Obstetric and gynaecological therapeutic procedures

Synonym
cancer of the uterus, endometrial cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - endometrial cancer, - intermediate risk, - low-risk, - sentinel lymph node

Outcome measures

Primary outcome

- the presence of micro- and macro metastasis

- to examine in how many cases SLN biopsy provides results that change adjuvant

treatment

Secondary outcome

- disease free survival data

- Quality of Life data

Study description

Background summary

Cancer of the endometrium has the highest prevalence of all gynecological cancers in North America and Europe. The incidence is still increasing due to prolonged life expectancy, changes in reproductive behavior and prevalence of overweight. Early stage endometrial cancer restricted to the uterus has an overall survival of 85-90%. The treatment of endometrial cancer is primarily surgery. However, an ongoing controversy in the management of endometrial cancer relates to lymphadenectomy. For patients with early stage endometrial cancer, randomized trials and a meta-analysis have shown that pelvic lymphadenectomy has no effect on overall or recurrence-free survival. A full lymphadenectomy can necessitate extensive dissection, which is time-consuming and involves morbidity. However, the trials on lymphadenectomy in early stage endometrial cancer did not take into account the contribution of sentinel lymph node (SLN) biopsy in reducing the risk of surgical complications and improving staging. Moreover, when lymph node status is unknown, indications for adjuvant therapies are on pathological features of surgical specimen of the primary tumor, exposing some patients to overtreatment and undertreatment.

Recently, Ballister showed that SLN biopsy with ultra-staging upstaged 10% of patients with presumed low-risk and 15% of patients with presumed intermediate risk.
SLN biopsy might be a good compromise between systemic lymph node dissection and no node dissection in women with low- or intermediate-risk endometrial cancer.
SLN biopsy seems a feasible method with a detection of the SLN in about 85%, and reliable in terms of negative predictive value (97% in the SENTI-ENDO study by Ballister et al.) and sensitivity (84%) when ultra-staging of SLNs is implemented.

The SLN biopsy is a well-known technique in the Netherlands as is has been used for over a decade in vulvar cancer. SLN biopsy in endometrial cancer should therefore be implemented easily in Dutch centers for gynecological oncology.

Study objective

1. To assess the feasibility of SLN identification in endometrial cancer.

2. To examine in how many cases SLN biopsy provides results that will tailor adjuvant treatment

3. To investigate if SLN biopsy in women with low- and intermediate-risk endometrial cancer will lead to better disease free and overall survival

Our aim is to individualize the care for patients with low-, and intermediate-risk endometrial cancer. Lymph node-tailored adjuvant treatment may lead to better recurrence-free and overall survival

Study design

142 patients with presumed low- or intermediate risk endometrial cancer will be included in this pilot.

Low-risk: type 1 endometrial cancer, stage 1A grade 1 or 2
intermediate-risk: type1endometrial cancer stage 1B grade 1 or 2.

To estimate the differentiation grade, every patient will undergo a pre-operative endometrial biopsy using the pipelle© sampling system. The pipelle has a sensitivity of 75% for all grades, but a sensitivity of 90% for diagnosis of either grade 1 or grade 2.

The sentinel node procedure: Four cervical injection of 0.2mL (20 MBq each) of Technetium-99m-labeled Nanocolloid with patente-blue of ICG will be given with a 25-gauge spinal needle at 3, and 9 o*clock positions deep and superficial. In case of subserosal application 2 injections are given subserosal.

Then a pause of 30 minutes is needed for both tracers to find their way through the lymphatic vessels. In the mean time preparation of the operation will take place in these 30 minutes.
The SLNs will be localized will be localized using a gamma probe (if laparoscopic approach the probe is inserted through a 12mm trocar) by selecting the areas with the highest radioactivity. Furthermore, the patent blue dye will be traced in the retro-peritoneum. Finally, a hysterectomy and bilateral salpingo-oophorectomy is performed.

Intervention

Patients with a positive sentinel node will be upgrade towards a stage 3A diases and treated accordingly with adjuvant external beam radiotherapy.

Study burden and risks

prior to the operation 4 cervical injections are needed. In case of subserosal appilcation 2 injections are given in the uterus subserosal during the operation. There is a risk of an allergic reaction of 0.6%, mainly pruritis and oedema, or hypotension (0.5%). These injections are given under anaesthesia before the start of the surgery.

- The operation procedure is extended wth SLN biopsy. This might give some extra blood loss and will extend the procedure with approximately 45 minytes. However, the SLN biopsy is a well-known technique in the Netherlands as it has been used for over a decade in vulvar cancer. SLN biopsy in endometrial cancer should therfore be implemented easily.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

low-risk endometrial cancer: type 1 endometrial cancer, stage 1A grade 1 or 2
Intermediate-risk endometrial cancer: type 1 endometrial cancer, stage 1B grade 1 or 2

Exclusion criteria

- high-risk endometrial cancer: type 2 endometrial cancer, endometrial cancer, 2 or higher or endometrial cancer type 1 stage 1B grade 2 or 3
- intermediate-risk endometrial cancer stage 1A grade 3
- women unfit for surgery
- women unfit for scintigram

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2016
Enrollment:	142
Type:	Actual

Ethics review

Approved WMO Date:	17-02-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-06-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-02-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	04-01-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-06-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-05-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-05-2020

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL52051.091.15