Nodal Metastasis in Endometrial Cancer: Detection Methods and Clinical Significance of lymph node micrometastasis

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This study consists of two phases. For more information about the study layout, see page 13-16 of the research protcol.The aim of phase 2:- To compare two different sentinel node techniques in patients, suspicious for endometrial cancer. The main...

Ethical review	Not approved
Status	Will not start
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON34586

Source
ToetsingOnline

Brief title
NOMETEC

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
endometrial cancer, uterine cancer

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht

Source(s) of monetary or material Support: Wij zijn voornemens - na goedkeuring van de METC - verschillende sponsors te benaderen voor subsidiëring van dit project.

Intervention

Keyword: Endometrial cancer, Micrometastasis, Sentinel node

Outcome measures

Primary outcome

PRIMARY OUTCOME PHASE 1

Which technique is most accurate and/or feasible, when being used as a method mapping the lymph node drainage routes and sentinel nodes of the uterus?

The two different techniques and drainage patterns will be compared to one and other. The main points of interest will be:

- feasibility

- patient friendliness

- the location of the sentinel nodes (pelvic and/or para-aortal)

- the level of para-aortal drainage (high and/or low)

PRIMARY OUTCOME PHASE 2

- The number of sentinel nodes found after injection with Technetium 99m labelled nanocolloid and blue (= detection rate)

- The reliability of the sentinel node procedure in high risk endometrial cancer, which will be determined by the false negative rate after histological examination of all removed nodes using the *gold standard* (= multiple

sectioning and hematoxylin and eosin staining)

- The feasibility and reliability of the OSNA CK 19 test as an in

intraoperative method to diagnose lymph node macro- and micrometastasis in

sentinel nodes of high risk endometrial cancer. Histopathological examination

(H&E) will be used as control method. In case of discordant cases

immunohistochemistry will be used as reference method. The reliability will be

defined by the true histological false negative rate.

Secondary outcome

SECONDARY OUTCOME PHASE 2

- Percentage of macro- and micrometastasis per lymph node station

- Number of nodes removed by laparotomic versus laparoscopic staging

- 5-Year recurrence free survival (RFS), disease specific (DSS) and overall

survival (OS) of sentinel node negative versus sentinel node positive patients

with high risk endometrial cancer (mainly those with micrometastasis)

Study description

Background summary

Endometrial cancer is the most frequent gynaecological cancer in industrialized countries. The disease has a relatively good prognosis. Those patients who die of the disease, die of distant metastases and recurrent disease.
Histological differentiation grade, tumour type and the depth of myometrial involvement, and - after surgery - lymph node involvement are the main prognostic factors in endometrial cancer.
Treatment of early stage endometrial cancer consists of surgical removal of the uterus and adnexa, peritoneal cytology and lymph node assessment.

Current non-invasive imaging techniques are restricted in their ability to

detect metastatic lymph node spread. On the other hand, the benefits of invasive surgery like a complete lymphadenectomy as part of the routine staging procedure (abdominal hysterectomy and BSO) remain controversial.

Both supporters and opponents of a routine lymphadenectomy agree that a pre- or peroperative non-invasive test to detect lymph node metastases would be valuable. Until now, only macroscopic nodal metastases can be visualized. Detailed pathological study of a lymph node with ultrastaging and immunohistochemical or PCR analysis can identify lymph node micrometastases that conventional methods would identify as negative for metastatic disease. Surgical techniques have been developed to identify and sample lymph nodes that can subsequently be submitted to such tests. It would therefore be timely to investigate such approaches also in endometrial cancer.

Study objective

This study consists of two phases. For more information about the study layout, see page 13-16 of the research protcol.

The aim of phase 2:

- To compare two different sentinel node techniques in patients, suspicious for endometrial cancer. The main points of interest will be: feasibility and patient friendlyness and the image on lymphoscintigraphy
- Mapping the lymphatic drainage system of the uterus

The aim of phase 2:

- To investigate the reliability of the sentinel node procedure in patients with high risk endometrial cancer
- Identification of nodes, in terms of prevalence and location, for subsequent ultrastaging
- Identify micrometases using a new peroperative *one step nucleic acid amplification* (OSNA, by SYSMEX) method
- Correlate results of presence and location of micrometastases with time to recurrence and survival.

Study design

Study lay-out phase 1 and 2: research protocol page 13-16
See also the schematic overview on page 25 and 26.

Study burden and risks

See answer question E9

Contacts

Public
Diakonessenhuis Utrecht

Veembroederhof 185
1019HD Amsterdam
Nederland
Scientific
Diakonessenhuis Utrecht

Veembroederhof 185
1019HD Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

The studie consists of two phases.
- Inclusion criteria for phase 1:
All women, suspicious for endometrial cancer, undergoing hysteroscopy and hysterectomy.
- Inclusion criteria for phase 2:
All women with high risk endometrial cancer, meaning that patients meet at least one of the following criteria:
> 50% myometrial invasion
differentiation grade 3
clearcell or serous papillary histology

carcinosarcoma
suspicious for extra-corporal spead

Exclusion criteria

Patients with contraindications for open abdominal or laparoscopic surgery will be excluded: cervical or pelvic infection, severe cardio-pulmonal or other co-morbidity contra-indicating extensive surgery and anaesthesia.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	245
Type:	Anticipated

Ethics review

Not approved

Date:	27-12-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL32601.100.10