

Nodal METastasis in high risk Endometrial Cancer (NOMETEC) PART I: Mapping the lymphatic drainage of the uterus: a feasibility study of the sentinel node procedure.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28134

Source

Nationaal Trial Register

Brief title

NOMETEC

Health condition

(High Risk) Endometrial Cancer

Sponsors and support

Primary sponsor: Diaconessenhuis Utrecht

University Medical Center Utrecht

University Medical Center St. Radboud Nijmegen

University Medical Center Maastricht

Source(s) of monetary or material Support: Diaconessenhuis Utrecht

University Medical Center Utrecht

University Medical Center St. Radboud Nijmegen

University Medical Center Maastricht

GE Healthcare

Intervention

Outcome measures

Primary outcome

Comparison of the two injection techniques considering their feasibility in mapping the pelvic and para-aortal lymphdrainage routes of the uterus.

Primary outcome parameters:

Total sentinel node detection rate per injection technique.

Secondary outcome

- Location of sentinel node detection: pelvic and/or para-aortal
- level of para-aortal sentinel node detection (high and/or low)

Study description

Background summary

Introduction:

Cancer of the endometrium has the highest prevalence of all gynaecological malignancies. In Europe, each year 9000 women die of this disease. The mortality rate is mostly the result of distant metastasis and recurrent disease.

The treatment of endometrial cancer is primarily surgical. A prognostic risk profile is assessed on the basis of distinct patient and tumour specific characteristics. The profile determines the choice of (adjuvant) therapy.

Involvement of the lymph nodes is one of the most important prognostic factors in most other malignant tumours. But the lymphatic drainage routes of the uterus are complex and the evidence on lymphatic spread of endometrial cancer is scarce. An estimated 20% of the patients with high risk endometrial cancer have lymph node involvement. Therefore the chance of nodal involvement in high risk patients is noteworthy and should be taken into account when treating endometrial cancer patients.

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 (remain controversial, given the potential morbidity).

Study design:

This study consists of a feasibility study (PART I) and a cross sectional diagnostic intervention study (PART II).

Aim:

The aim is to investigate the feasibility and reliability of the sentinel node procedure for intra-/preoperative lymph node mapping in patients with high risk endometrial cancer. Furthermore, we are interested in the prevalence of micrometastasis and para-aortal metastasis.

Population:

The feasibility study (NOMETEC PART I) will include all women, undergoing a hysteroscopic curettage and a hysterectomy because of suspicion for a (malignant) lesion of the endometrium.

NOMETEC PART II investigates the reliability of the sentinel node procedure in high risk endometrial cancer patients, meaning that the tumour meets one of the following criteria: differentiation grade 3, more than 50% myometrium invasion, suspicious for extra-corporal spread, serous papillary, clear cell or carcinosarcoma tumour type.

Main outcome parameter:

NOMETEC PART I is a feasibility study comparing two different tracer administration techniques, meant for sentinel lymph node mapping. The main outcome parameter of PART I is the sentinel node detection rate for the two methods.

The main outcome parameter of NOMETEC PART II is the reliability of the sentinel node procedure in high risk endometrial cancer patients, represented by the true and false negative rate after histopathological examination of the removed lymph nodes.

Secondary outcome parameter:

In NOMETEC PART I the procedure of both injection methods will be compared for patient and doctor friendliness. We will ask both parties to fill out a short questionnaire.

The secondary outcome parameters of NOMETEC PART II will be the prevalence of para-aortal metastasis and the prevalence of micrometastasis.

The sentinel nodes will be submitted to several “ultrastaging” methods, that can identify micrometastasis and isolated tumour cells in nodes, that conventional methods would identify as negative for metastatic disease.

Study objective

The aim is to investigate the feasibility of the sentinel node procedure using hysteroscopic submucosal versus laparoscopic/tomic subserosal injection of Technetium labelled nanocolloid in the uterus.

Study design

July 2011; Approval Verenigde Commissies Mensgebonden Onderzoek (VCMO)

February 2012; Start patient recruitment

Oktober 2013; Collaboration with University Medical Center St. Radboud Nijmegen and University Medical Center Maastricht

Intervention

Diagnostic and pre-operative work-up of the participants will be in accordance with current clinical practice and protocols. During the ambulant hysteroscopic procedure submucosal injection (SMI) of 250 MBq in 4 doses of 1 ml Technetrium labelled nanocolloid will be performed. Subsequently, with a time interval of at least 1 week, the same patient will undergo a hysterectomy during which a subserosal injection (SSI) of the same radioactive tracer will be performed.

Contacts

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Eligibility criteria

Inclusion criteria

- All women, undergoing a diagnostic or therapeutic hysteroscopy because of suspicion for a (benign) lesion of the endometrium (polyps, small myoma, ...)
- All women, undergoing a hysteroscopic curettage and a hysterectomy because of suspicion for a (malignant) lesion of the endometrium.

Exclusion criteria

Contra-indication for hysteroscopy and/or open abdominal surgery and/or laparoscopic surgery: cervicitis, PID, severe cardiopulmonal or other co-morbidity.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2012
Enrollment:	40

Type: Anticipated

Ethics review

Positive opinion

Date: 30-10-2013

Application type: First submission

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
NTR-new	NL4078
NTR-old	NTR4229
CCMO	NL
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A