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.

Gepubliceerd: 30-10-2013 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28134

Bron
Nationaal Trial Register

Verkorte titel
NOMETEC

Aandoening

(High Risk) Endometrial Cancer

Ondersteuning

Primaire sponsor: Diakonessenhuis Utrecht
University Medical Center Utrecht
University Medical Center St. Radboud Nijmegen
University Medical Center Maastricht
Overige ondersteuning: Diakonessenhuis Utrecht
University Medical Center Utrecht

University Medical Center St. Radboud Nijmegen
University Medical Center Maastricht
GE Healthcare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-10-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A