Sentinel node biopsy in Low- and Intermediate endometrial cancer Management

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The proportion of patients with a positive sentinel lymph node(at least one macro- or micrometastasis) which alter the adjuvant therapy

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22329

Bron
NTR

Verkorte titel
SLIM study

Aandoening

Endometrial cancer (early stage)
Sentinel lymph node
Indocyanine green

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: initiator sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The proportion of patients with a positive sentinel lymph node (at least one macro- or micrometastasis) with a change in adjuvant therapy.

Toelichting onderzoek

Achtergrond van het onderzoek

The treatment of endometrial cancer (EC) is primarily surgery (removal of uterus and adnexa). There is an ongoing controversy in the management of EC relates to lymphadenectomy. Randomized trials and a meta-analysis have shown that pelvic lymphadenectomy has no effect on overall or recurrence-free survival, but can lead to longer operation time and morbidity [Kitchener et al. 2009, Benedetti et al. 2008, May et al. Cochrane Rev 2010] 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.

Recent studies showed that SLN biopsy with ultra-staging upstaged 10% of patients with presumed low-risk and 15% of patients with presumed intermediate risk [Ballister et al. 2008, 2011;Abu Rustum 2014]. As involvement of lymph nodes has been proven to be one of the most important prognostic factors in other malignant tumors, SLN biopsy might be a good compromise between systemic lymph node dissection and no node dissection in women with low- or intermediate-risk EC.

When the 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. Introducing SNP in the treatment of EC will lead to only giving adjuvant treatment when women are truly at risk.

SLN biopsy in EC can be performed with cervical injection prior to surgery using indocyanine green with high detection rates 92-96% and negative predictive values 98-99%.

Doel van het onderzoek

The proportion of patients with a positive sentinel lymph node(at least one macro- or micrometastasis) which alter the adjuvant therapy

Onderzoeksopzet

Histological evaluation of the sentinel lymph node with ultrastaging and immunohystochemistry after surgery.

Onderzoeksproduct en/of interventie

sentinel lymph node before the operation (hysterectomie and adnexa)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age 18 years

Histological confirmed endometrioid adenocarcinoma of the endometrium grade 1 or 2 on microcurettage

Low-risk: type 1 endometrial cancer, stage IA grade 1 or 2 or Intermediate-risk: type 1 endometrial cancer, stage IB grade 1 or 2

WHO-performance 0-2

WBC > 3.0x 109/L, platelets > 100 x 109/L, creatinine clearance > 60ml/min

CT-scan with no evidence of distant metastases

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients with high-risk type 1 endometrial cancer stage (IB grade 3) or type 2 endometrial cancer (defined as > 10% of the specimen is serous or clear cell type) of any grade and stage.

Patients with intermediate- risk stage IA grade 3 type 1 endometrial cancer

Patients with contraindications to surgery, anesthesia or pelvic radiation.

Patients with an allergic reaction on Technetium 99m-Nanocolloid, ICG or patent-blue

Patients with previous pelvic or para-aortic lymph node dissection or sampling for a previous malignancy

Previous pelvic or abdominal radiotherapy

Patients with evidence of pelvic and/or distant metastasis

Pregnancy

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	142
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-04-2016
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	NL5659
NTR-old	NTR5794
CCMO	NL49827.091.14

Resultaten

Samenvatting resultaten
2020