The bilateral sentinel node detection rate of fluorescent indocyanine green compared to 99mTc and blue dye in the sentinel node procedure in stage I-IIA cervical cancer

Gepubliceerd: 30-10-2020 Laatst bijgewerkt: 18-08-2022

Intraoperative ICG with NIR fluorescence imaging provides non-inferior bilateral detection rates of SLNs in early-stage cervical cancer compared with the current standard of care, 99mTc and blue dye.

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

Samenvatting

ID

NL-OMON28788

Bron
Nationaal Trial Register

Verkorte titel
FluoreSENT study

Aandoening

Cervical cancer

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: University Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The intraoperative bilateral SLN detection with ICG versus a combination of 99mTc and blue dye in patients with cervical cancer undergoing a SLN procedure.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: We hypothesize intraoperative indocyanine green (ICG) with near-infrared (NIR) fluorescence imaging provides non-inferior bilateral detection rates of sentinel lymph nodes (SLNs) in early-stage cervical cancer compared with the current standard of care, Technetium-99m nanocolloid (99mTc) with preoperative SPECT-CT in combination with intraoperative blue dye. In daily practice, switching to ICG offers advantages over the use of 99mTc and blue dye; ICG is cheaper, non-radioactive, logistically more attractive, and leads to less burden on the patient (shorter admission, injection under anaesthesia, potentially less morbidity).

Objective: To evaluate the bilateral SLN detection rate of intraoperative ICG with NIR fluorescence imaging compared to the current standard of care of 99mTc (with preoperative SPECT/CT) and blue dye.

Study design: We plan a cross-sectional, monocentre, non-inferiority study with a paired comparison of both SLN modalities in a single sample of patients. Thus, all patients undergo mapping with ICG and NIR fluorescence imaging followed by mapping with 99mTc and blue dye. The surgeons will be blinded for the pre-operative outcome of SPECT-CT to avoid biased detection with ICG.

Study population: Patients with early-stage cervical cancer who receive primary surgical treatment (FIGO stage IA – IB2 or IIA1).

Intervention: SLN procedure with NIR fluorescence imaging after peritumoural injection of ICG (5mg) in adjunct to the current standard of care.

Main study parameters/endpoints: The main endpoint of this study is bilateral SLN detection rate of the different modalities (i.e. detection of at least one SLN in each hemipelvis). Secondary endpoints include overall SLN detection rate (i.e. detection of at least one SLN), diagnostic accuracy in terms of tumour positivity of the different modalities (sensitivity and false negatives; defined as patients with tumour-negative SLNs and tumour-positive non-SLNs), with pelvic lymph node dissection (PLND) as gold standard to confirm tumour positive lymph nodes (part of current standard-of-care), the number of SLNs detected, concordance of SLN localisation with different modalities, cost-effectiveness in terms of costs related to the percentage increase in bilateral detection rate, patient satisfaction, and usability of

fluorescence guided surgery.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: As we compare strategies for SLN procedure that are already applied in current daily practice (99mTc with blue dye) or on large scale in research setting for cervical cancer (ICG), no additional risks or burdens are expected from these interventions. Since ICG with NIR fluorescence imaging is used in adjunct to the standard procedure, the total operation time might be slightly longer (estimated at 15 minutes). The extra time will only be a small fraction of the total duration of the operation (240 minutes) and will therefore entail only minimal risks of prolonged anaesthesia. In very rare cases an allergic reaction to ICG has been reported (< 1/10.000 cases). In order to minimize this risk, patients with an severe allergy for iodine and those with a renal insufficiency are excluded from this study.
Patients receive an additional questionnaire (EORTC IN-PATSAT32) regarding patients' satisfaction with the oncological care and services.1 This questionnaire is validated and the results can help us to place the outcome measures in context of the patients' experience. No additional blood samples, site visits or physical examinations are needed during this study.

Doel van het onderzoek

Intraoperative ICG with NIR fluorescence imaging provides non-inferior bilateral detection rates of SLNs in early-stage cervical cancer compared with the current standard of care, 99mTc and blue dye.

Onderzoeksopzet

Intraoperative and postoperative (pathological assessment) measurements

Onderzoeksproduct en/of interventie

SLN procedure with NIR fluorescence imaging after peritumoral injection of ICG (5mg) in adjunct to the current standard of care

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥18 years and able to provide informed consent
- A histopathologically proven primary malignancy of the cervix uteri
- FIGO stage IA1-IB2 or IIA1 (according to the FIGO 2018 guidelines)
- Radical surgery is planned including a SLN procedure

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pregnancy or current breastfeeding (confirmation by a pregnancy test is the current standard of care), because of the unknown risks of ICG on
- Renal insufficiency stage 3 or 4, because of the increased risk of anaphylactic reaction
- Prior allergic reaction to ICG, 99mTc or patent blue
- Prior severe allergic reaction to iodine

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
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:	01-03-2021
Aantal proefpersonen:	101
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	30-10-2020
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	NL9011
Ander register	METC Utrecht : METC 21-014

Resultaten

Samenvatting resultaten
N/A