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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28788

Source
NTR

Brief title
FluoreSENT study

Health condition

Cervical cancer

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Overall SLN detection rate;
2. Sensitivity and false negative rate of ICG and 99mTc and blue dye, with pelvic lymph node dissection (PLND) as gold standard to confirm tumour positive lymph nodes (part of current standard-of-care);
3. The number of SLNs identified with NIR fluorescence, radioactivity and blue staining.
4. The correlation (concordance) between NIR fluorescent, radioactive and blue stained SLNs, in terms of anatomical location of the detected SLN;
5. Adverse events of ICG, 99mTc and/or blue dye;
6. The time to complete SLN detection with ICG versus 99mTc + blue dye (including the time to detect separate SLNs);
7. Cost-effectiveness comparison of ICG versus 99mTc and blue dye SLN detection;
8. Patient satisfaction with the oncological care and procedure (IN-PATSAT32 questionnaire);
9. Surgical evaluation of the usability of fluorescence imaging measured with questionnaires.

Study description

Background summary

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.

Study objective

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.

Study design

Intraoperative and postoperative (pathological assessment) measurements

Intervention

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

Contacts

Public
UMC Utrecht
Ilse Baeten

+31 88 75 530 68
Scientific
UMC Utrecht
Ilse Baeten

+31 88 75 530 68

Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2021
Enrollment:	101
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	30-10-2020
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	NL9011

Register	ID
Other	METC Utrecht : METC 21-014

Study results

Summary results
N/A