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

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This study has been transitioned to CTIS with ID 2024-511966-36-00 check the CTIS register for the current data. To evaluate the bilateral SLN detection rate of intraoperative ICG with NIR fluorescence imaging compared to the current standard of…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON50824

Source
ToetsingOnline

Brief title
FluoreSENT study

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Stage IA-IIA cervical cancer; cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Indocyanine Green, Sentinel Lymph Node Biopsy, Technetium, Uterine Cervical Neoplasms

Outcome measures

Primary outcome

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). Bilateral detection rate is defined as the proportion of patients with at least one SLN detected in each hemipelvis.

Secondary outcome

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 with the provided care, and usability of fluorescence guided surgery.

Study description

Background summary

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).

Study objective

This study has been transitioned to CTIS with ID 2024-511966-36-00 check the CTIS register for the current data.

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.

Intervention

ICG with NIR fluorescence imaging.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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)
-Renal insufficiency stage 3 or 4
-Prior allergic reaction to ICG, 99mTc or patent blue
-Prior severe allergic reaction to iodine

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-06-2021
Enrollment:	101
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Verdye
Generic name:	Indocyanine green
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-01-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-03-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-08-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-02-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EU-CTR	CTIS2024-511966-36-00

Register	ID
EudraCT	EUCTR2020-005134-15-NL
CCMO	NL75722.041.20
Other	NL9011