SENSEI® system for detecting sentinel lymph nodes in cervical cancer

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We hypothesize that the SENSEI® laparoscopic tethered gamma probe will enable a more accurate and faster detection of sentinel lymph nodes in comparison to the rigid laparoscopic gamma probes currently used in cervical cancer sentinel node biopsy.

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

Samenvatting

ID

NL-OMON28547

Bron
NTR

Verkorte titel
TBA

Aandoening

Early-stage cervical cancer

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: UMC Utrecht, LightPoint Medical Ltd.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sentinel lymph node detection rate (defined as the in vivo detection of at least one sentinel lymph node in each patient).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: We evaluate the technical feasibility and usability of the SENSEI® laparoscopic tethered gamma probe system for detection of sentinel lymph nodes (SLNs) in patients with early-stage cervical cancer. The rigid laparoscopic gamma probe currently used for robot-assisted laparoscopic surgeries in cervical cancer has limited manoeuvrability and control which restricts nodal identification.

Device name: SENSEI® laparoscopic tethered gamma probe system, LightPoint Ltd. The SENSEI® system comprises of a laparoscopic tethered gamma probe connected to a main powered control unit.
Product Regulatory Status: CE-marked medical device for sentinel lymph node biopsy in prostate, endometrial and cervical cancer.

Objective: To examine the safety and feasibility of the SENSEI® laparoscopic tethered gamma probe system for sentinel lymph node biopsy (SLNB) with 99mTc-nanocolloid in patients with early-stage cervical cancer.

Study design: Investigator initiated feasibility study, single arm.

Study population: Women with early-stage cervical cancer (FIGO stage IA – IB2 or IIA1) scheduled for primary surgical treatment including SLNB who have no contraindications for use of 99mTc-nanocolloid.

Sample size: 10 patients (feasibility study).

Study duration: An estimated recruitment period of six months.

Intervention: SLNB with use of SENSEI® laparoscopic tethered gamma probe system for detection of 99mTc-nanocolloid.

Study procedures: The preoperative preparations (e.g. injecting 99mTc-nanocolloid and performing a SPECT-CT one day before surgery) will proceed according to the current standard protocol. On the day of surgery, the SLNB will start with the use of the SENSEI® laparoscopic tethered gamma probe system (after calibration with a Cobalt-57 sealed source at the OR). The SLN detection and anatomical location with the investigational probe is reported. Subsequently, the conventional rigid gamma probe (Europrobe 3 Coelioscopique, Euromedical Instruments, Le Chesnay, France) will be used to check the correct identification of SLNs (in vivo). The SLNs will then be excised and radioactivity is also checked ex vivo with both probes (according to the current standard of care). The rest of the robot-assisted procedure will be performed according to the standard institutional protocols, including the frozen section examination of the SLNs and a bilateral pelvic lymph node dissection.

Main study parameters/endpoints: The main study parameter is the SLN detection rate (defined as the detection of at least one SLN in each patient) with the SENSEI® laparoscopic

tethered gamma probe. Secondary endpoints include the duration of the SLNB, number of SLNs detected, and intraoperative adverse events of the SENSEI® system in comparison to the conventional rigid laparoscopic gamma probe. Also, the overall ease of use of the SENSEI® laparoscopic tethered gamma probe system will be evaluated (validated with a questionnaire filled in by the surgeons).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: We expect no additional burden or physical discomfort to be associated with participation. The risk associated with participation in this feasibility study is considered to be nihil since the SLN detection rates with the SENSEI® laparoscopic tethered gamma probe will be validated with the conventional rigid gamma probe. Therefore, there is no risk of lower SLN detection rates in these patients. We don't expect the use of the SENSEI® laparoscopic tethered gamma probe to constitute any additional intraoperative or postoperative risks compared to conventional rigid laparoscopic gamma probe guided procedures. In the current procedure patients are already exposed to radiation of 99mTc-nanocolloid, so this will not result in additional risks. The SENSEI® laparoscopic tethered gamma probe is non-radiation emitting. The SENSEI® laparoscopic tethered gamma probe has undergone comprehensive preclinical testing, which demonstrates proof of concept and safety for its intended use. A full Risk Management Review has been conducted in accordance with ISO 14971:2012.
It is hypothesized that the small size of the SENSEI® laparoscopic tethered gamma probe and the ability to manipulate the probe with the laparoscopic forceps will enable more accurate and complete detection of SLNs in comparison to the rigid laparoscopic gamma probes currently available. This study offers the potential benefits of more complete SLN (and cancer) detection to participants.

Doel van het onderzoek

We hypothesize that the SENSEI® laparoscopic tethered gamma probe will enable a more accurate and faster detection of sentinel lymph nodes in comparison to the rigid laparoscopic gamma probes currently used in cervical cancer sentinel node biopsy.

Onderzoeksopzet

Primary and secondary outcomes will be assessed during (or directly after) surgical procedure.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following 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);
- Robot-assisted radical surgery is planned with a SLNB and bilateral pelvic lymph node dissection (current standard of care)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Pregnancy or current breastfeeding (confirmation by a pregnancy test is the current standard of care).
- Prior allergic reaction to 99mTc-nanocolloid.

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 gestopt
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	10
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	23-03-2021
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	NL9358
Ander register	METC Utrecht : METC 21-019 nWMO

Resultaten