SENSEI® system for detecting sentinel lymph nodes in cervical cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28547

Source
NTR

Brief title
TBA

Health condition

Early-stage cervical cancer

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: UMC Utrecht, LightPoint Medical Ltd.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

- The duration of the sentinel lymph node biopsy (SLNB), defined as the time between the in vivo introduction of the SENSEI® gamma probe and the removal of the SENSEI® gamma probe after checking the surgical site for residual radioactivity (the last step of the SLNB). Track of time is temporarily stopped when the rigid gamma probe is used for validation;
- The number of sentinel lymph nodes detected with the SENSEI® system in comparison with the pre-operative Single Photon Emission Computed Tomography (SPECT)-CT and the conventional rigid probe;
- The intraoperative adverse events of the SENSEI® system in comparison to the conventional rigid laparoscopic gamma probe;
- The ease of use of the SENSEI® laparoscopic tethered gamma probe system; this will be validated with a questionnaire filled in by the surgeons postoperatively. This questionnaire is based on the questionnaire constructed by LightPoint Medical Ltd which used in other clinical trials on the SENSEI® laparoscopic tethered gamma probe system (mainly prostate cancer).

Study description

Background summary

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.

Study objective

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.

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

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)

Exclusion criteria

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.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2021
Enrollment:	10
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	23-03-2021
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	NL9358
Other	METC Utrecht : METC 21-019 nWMO

Study results