SENtinel lymph node mapping with GAllium-68-tilmanocept PET/CT in high/high-intermediate risk endometrial cancer: a proof-of-concept study

Published: 08-08-2022
Last updated: 10-01-2025

This study has been transitioned to CTIS with ID 2024-516708-40-00 check the CTIS register for the current data. The primary objective of this proof-of-concept study is to evaluate feasibility of 68Ga-tilmanocept PET/CT for SLN mapping in patients...

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

Summary

ID

NL-OMON56288

Source
ToetsingOnline

Brief title
SENGA study

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Endometrial cancer, uterine cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W,Dr. C.J. Vaillant Fonds

Intervention

Keyword: Endometrial cancer, Radiotracer, Sentinel lymph node mapping

Outcome measures

Primary outcome

Primary endpoint is the feasibility of the SLN procedure using 68-Gatilmanocept PET/CT in patients with high/high-intermediate risk endometrial cancer. The feasibility is assessed by the SLN detection rate of 68Ga-tilmanocept PET/CT. The SLN detection rate of PET/CT is defined as the detection of a PET-avid node.

Secondary outcome

- Correlation between SLN detection rate and anatomical location of SLNs with preoperative 68Ga-tilmanocept PET/CT versus intraoperative ICG with NIR fluorescence; - Pathological status of the SLNs: negative, macrometastasis (diameter>2.0 mm), micrometastasis (diameter between 0.2 and 2.0 mm) or isolated tumour cells (diameter <0.2 mm or individual tumour cells)); - Adverse events related to SLN mapping with 68Ga-tilmanocept PET/CT up to one hour post-PET/CT (graded by Common Terminology Criteria for Adverse Events (CTCAE) v5.0).

Study description

Background summary

Endometrial cancer is the most prevalent gynaecological cancer in the Netherlands, affecting more than 2000 women per year (IKNL). When metastasized

to the lymph nodes, it impacts stage, prognosis and adjuvant therapy, highlighting the importance of accurate nodal assessment. Lymphatic mapping to identify SLNs, i.e. the first nodes along the drainage route of a tumour, is a frequently studied practice in managing endometrial cancer. Currently, indocyanine green (ICG) with near-infrared fluorescence imaging is the widely accepted sentinel lymph node (SLN) mapping technique in endometrial cancer. Use of ICG is limited by a tissue penetration of <1cm, especially in patients with high BMI. Another limitation is its rapid spreading towards higher echelon nodes, leading to a higher number of lymph nodes removed compared to more conventional techniques with a radiotracer and blue dye. Improving the SLN mapping technique, with more accurate identification of SLNs, may increase bilateral detection and decrease tissue damage. We propose that preoperative imaging, which can guide the surgeon towards the true SLN intraoperatively, could improve SLN mapping in patients with endometrial cancer. The use of radiotracer Gallium-68-tilmanocept (68Ga-tilmanocept) enables preoperative PET/CT. Tilmanocept has sustained retention at the SLNs which provides low second echelon node accumulation compared to ICG. Use of 68Ga-tilmanocept could result in increased bilateral detection of SLNs and better differentiation between SLN(s) and second echelon nodes.

Study objective

This study has been transitioned to CTIS with ID 2024-516708-40-00 check the CTIS register for the current data.

The primary objective of this proof-of-concept study is to evaluate feasibility of 68Ga-tilmanocept PET/CT for SLN mapping in patients with stage I-II high/high-intermediate risk endometrial cancer. Secondary objectives are: - To investigate the correlation between SLN detection rate and anatomical location of SLNs with preoperative 68Ga-tilmanocept PET/CT versus intraoperative ICG with NIR fluorescence; - To assess pathological status of the SLNs: tumour negative, macrometastasis (diameter >2.0 mm), micrometastasis (diameter between 0.2 and 2.0 mm) or isolated tumour cells (diameter <0.2 mm or individual tumour cells); - To investigate adverse events related to SLN mapping with 68Ga-tilmanocept PET/CT up to one hour post-PET/CT (graded by Common Terminology Criteria for Adverse Events (CTCAE) v5.0).

Study design

The proposed study is a non-randomised, single-arm proof-of-concept study conducted in the UMC Utrecht. All included subjects will undergo preoperative 68Ga-tilmanocept PET/CT (PET + contrast enhanced CT-abdomen) for the purpose of SLN detection, in adjunct to intraoperative SLN detection with ICG (considered standard-of-care).

Study burden and risks

Extra burden for subjects concerns one additional site visit for the cervical injection of a radiotracer followed by PET/CT imaging, with a total duration of two hours (including one hour waiting time). The preoperative injection with 68Ga-tilmanocept could be accompanied by pain or irritation at the point of injection, but this is rare. The additional site visit does not delay the scheduled surgerical treatment.

The extra administration of 10 MBq 68Ga-tilmanocept followed by PET/CT exposes subjects to a radiation of 6.3 mSv, which is considered an acceptable radiation burden to the patient. We advise patients not to enroll in another trial with exposure to radiation in the near future.

Subjects may benefit from this study since the SLN detection rate may be increased by adding 68Ga-tilmanocept PET/CT to the diagnostic procedure.

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

- Clinical FIGO 2012 stage I-II high/high-intermediate risk endometrial cancer;
- Scheduled for robot-assisted full pelvic and para-aortic staging;
- Age >=18 years and able to provide informed consent.

Exclusion criteria

- Pregnancy or current breastfeeding (in women at a fertile age with a possibility of pregnancy, confirmation by a pregnancy test is current standard of care);
- Prior severe allergic reaction to iodine;
- Severe renal insufficiency (stage 3 or 4);
- Clinical or radiological evidence of metastatic disease.

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-03-2023
Enrollment:	10
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	N/A
Generic name:	Gallium-68-tilmanocept

Ethics review

Approved WMO Date:	08-08-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-09-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	16-08-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-08-2023
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-07-2024
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-07-2024
Application type:	Amendment
Review commission:	METC NedMec

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	CTIS2024-516708-40-00
EudraCT	EUCTR2022-001237-37-NL
ClinicalTrials.gov	NCT05446324
CCMO	NL81058.041.22