A feasibility study on Cerenkov Luminescence Imaging during prostate cancer surgery using Gallium-68 PSMA

No registrations found.

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

Summary

ID

NL-OMON28042

Source
Nationaal Trial Register

Brief title
CLIPPS

Health condition

Primary prostate cancer

Sponsors and support

Primary sponsor: This research is supported by KWF Kankerbestrijding and Technology Foundation STW, as part of their joint strategic research programme ‘Technology for Oncology’ (Grant number 15175).
Source(s) of monetary or material Support: This research is supported by KWF Kankerbestrijding and Technology Foundation STW, as part of their joint strategic research programme ‘Technology for Oncology’ (Grant number 15175).

Intervention

Outcome measures

Primary outcome

The objective of this study is to assess the feasibility of 68Ga-PSMA CLI for intra-operative analysis of prostate surgical specimens.

Secondary outcome

Radiation dosimetry to the OR personnel during the radical prostatectomy .

Study description

Background summary

Prostate cancer is the second most common cancer in the world and is still the leading cancer among men in the Netherlands with over 10,000 men diagnosed each year. Surgery remains one of the primary treatment options for the disease, yet it is frequently unsuccessful with cancer left behind in a substantial number of men (11-38%). The incomplete removal of cancer during prostate cancer surgery is associated with increased likelihood of disease recurrence and poor patient outcomes. Also, these patients may undergo debilitating adjuvant therapies following surgery that have a marked impact on the patient's quality of life. Complete surgical excision is challenging, as the surgeon is unable to distinguish between cancerous and non-cancerous tissue during surgery. There is therefore an urgent medical need for surgeons to be able to visualize cancer during an operation to ensure that all of the cancer is completely removed. In this study the feasibility of Gallium-68-Prostate Specific Membrane Antigen (68Ga-PSMA) Cerenkov Luminescence Imaging (CLI) will be investigated as a technique for intraoperative analysis of prostate surgical specimens. This molecular optical technology involves imaging of Cerenkov photons, emitted from radiopharmaceuticals concentrated in cancerous tissue, using an intraoperative CLI system called LightPath®. The primary objective is to assess the feasibility of intra-operative analysis of prostate surgical specimens using 68Ga-PSMA CLI.
Study design: This study is a single-centre, prospective clinical feasibility study.
Study population: This study will include 30 high risk primary prostate cancer patients who are planned to undergo radical prostatectomy.
Intervention (if applicable): Intravenous 68Ga-PSMA injection and ex vivo CLI imaging of excised prostate specimen.
Main study parameters/endpoints: The objective of this study is to assess the feasibility of 68Ga-PSMA CLI for intra-operative analysis of prostate surgical specimens.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The subjects included in this study will receive a certain radiation exposure from the radiotracer 68Ga-PSMA that will be administered in this study. The expected radiation dose will approximately be 2 millisievert (mSV), which fall within acceptable limits.

Study objective

In this study the feasibility of the CLI will be tested to detect positive surgical margins during surgery. This will be compared to standard histopathology. When there is a good correlation

between this detection, this intra-operative margin assessment can guide the surgeon, and may help making the decision to operate nerve sparing or not. By providing information where the tumour is located relative to the neural-vascular bundles.

Study design

NA

Intervention

Intravenous 68Ga-PSMA injection and ex vivo CLI imaging of excised prostate specimen.

Contacts

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Eligibility criteria

Inclusion criteria

- Primary prostate cancer >18 year
- Eligible for PSMA PET scan (PSA≥20 ng/mL or ≥cT3 or Gleason ≥7)
- Tumour larger than 1.5cm on MRI.
- Signed informed consent
- Voluntary understanding
- Scheduled for radical prostatectomy surgery
- PSMA uptake on pre-operative 68Ga-PSMA PET scan

Exclusion criteria

- Usage of Indocyanine green (ICG) during surgery

- No PSMA uptake on clinical PET/CT-scan
- Subjects who have an existing medical condition that would compromise their participation in the study

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:	Recruiting
Start date (anticipated):	22-05-2019
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
This is a prospective, single-centre pilot observational study with invasive measures to assess the feasibility of 68Ga-PSMA CLI for intra-operative analysis of prostate surgical specimens.

The study will include 30 subjects with moderate to high risk prostate carcinoma, who underwent a 68Ga-PSMA PET/CT-scan and had a PSMA positive local tumor and are planned for a radical prostatectomy surgery. To be eligible for a PSMA PET/CT scan patients should have a stage≥T3 or Gleason Score≥7 or PSA≥20ng/mL. Subjects will be approached based on the outcomes of their clinical 68Ga-PSMA PET/CT-scan and MRI scan (tumour≥2cm). Subjects will be asked to participate in this study, receive written information and the informed consent form. After interim analysis, smaller tumour sizes could be included.

Ethics review

Positive opinion

Date:	04-11-2019
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	NL8256
Other	METC AVL : METC19.0814/N18CLI

Study results

Summary results

olde Heuvel J, de Wit-van der Veen BJ, Vyas KN, Tuch DS, Grootendorst MR, Stokkel MPM, et al. Performance evaluation of Cerenkov luminescence imaging: a comparison of 68Ga with 18F. EJNMMI Phys 2019;6:17.