99mTechnetium based PSMA-Radioguided Assisted surgery for prostate Cancer feasibility Study

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The potential use of 99mTechnetium (99mTc)-based PSMA-radioguided surgery (99mTc-PSMA-RGS) for salvage lymphadenectomy for PC.

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

Summary

ID

NL-OMON50122

Source
ToetsingOnline

Brief title
TRACE

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: NKI-AVL

Intervention

Keyword: 99mTechnetium-PSMA, prostate cancer, radiotherapy, surgery

Outcome measures

Primary outcome

• Investigation of the feasibility of 99mTc-PSMA RGS in salvage lymph node dissection in men with recurrent PC after intravenously injection of 99mTc-PSMA-I&S.

Secondary outcome

• To evaluate if 99mTc-PSMA-RGS aids intra-operative localization of nodes that had previously been detected as positive on pre-operative PSMA PET/CT to ensure PC lymph nodes are not missed at operative salvage lymph node dissection.

• To establish optimal imaging protocol for pre-operative 99mTC-PSMA-I&S SPECT/CT and interval between imaging and surgery.

• Determine the diagnostic accuracy of 99mTc-PSMA-I&S RGS compared to histologic evaluation after either 15-19 hours compared to 20-24 hours after intravenously injection of 99mTc-PSMA-I&S.

• Complete biochemical response (PSA <0.2ng/mL) 30 days, 3, 6, 12 and 24 months after salvage surgery without adjuvant prostate cancer specific (hormonal or radiation) treatment.

• Diagnostic accuracy of 99mTc-PSMA-I&S radioguided salvage surgery compared to histologic evaluation

• Diagnostic accuracy of preoperative Ga-PSMA-PET or 18F-DCFPyl-PSMA-PET and 99mTc-PSMA-SPECT/CT compared to histologic evaluation.

• To assess the number of in field recurrences (recurrence measured by use of

PSMA PET/CT in the template of 99mTc-PSMA-RGS supported salvage lymph node dissection) in men with biochemical recurrence.

• Assessment of 99mTc-PSMA-I&S injection-related as well as surgery-related 30- and 90-day complication rate according to Clavien-Dindo.

Study description

Background summary

Prostate cancer (PC) is the most common cancer in men. The ability to accurately determine the location and extent of lymph node involvement in PC has significant implications on decision-making regarding treatment modality and ongoing management planning. The European Association of Urology PC guidelines recommend, for staging in clinically localized intermediate and high-risk cancer, a pelvic lymph node dissection (PLND). Despite this, 25-35% of the PC patients who are treated with curative intent with radical prostatectomy (RP) and extended PLND will develop clinically significant biochemical recurrence with local and/or distant disease. Even with an extended template dissection including external iliac, hypogastric and obturator nodes, 35% of lymph nodes potentially containing PC will not be removed at surgery, either being out of the standard surgical field, or being missed within. Improvements in pre-operative and intra-operative techniques for detection of lymph node metastases may result in a shift towards increased cure and lower biochemical recurrence rates in patients with primary diagnosed PC and/or in patients with recurrent PC with lymph node metastasis in pelvis and retroperitoneum.

Study objective

The potential use of 99mTechnetium (99mTc)-based PSMA-radioguided surgery (99mTc-PSMA-RGS) for salvage lymphadenectomy for PC.

Study design

An investigator initiated, prospective, non-randomized, pilot feasibility study.

Study burden and risks

Other than either one or two preoperative 99mTc-PSMA scintigraphic imaging procedures including SPECT/CT scans (with a single intravenous injection of

99mTc-PSMA-I&S), this study will not result in any procedures different from the standard procedures

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

• Male, aged >= 18 years.
• Hormone-sensitive recurrent protstate cancer after radical prostatectomy , external beam radiotherapy or brachytherapy
• Less than a number of 4 soft tissue lesions (lymph node; connective tissue) within the pelvis or retroperitoneum with sufficient PSMA expression (>=3 times regional vascular activity level) as determined by PSMA-based PET
• PSA-value <4ng/mL
• Had a PSMA PET/CT within 60 days before surgery

• Suitable for salvage lymph node dissection, as per institutional guidelines.
• WHO performance status 0,1, or 2.
• Written informed consent.

Exclusion criteria

• Suspicion of local recurrent prostate cancer within the prostatic fossa not treatable by surgery
• Nonregional lymphadenopathy (cM1a) or distant metastases (cM1b/c) as assessed by preoperative PSMA PET/CT.
• Ongoing androgen deprivation therapy (ADT) or within 6 months prior to surgery.
• Severe claustrophobia interfering with PET/CT or SPECT/CT scanning

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-05-2020
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	04-03-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	29-10-2020
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
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL68290.031.18