Quantitative Margin Assessment using high-resolution Positron Emission Tomography - Computed Tomography

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Primary objective:To investigate the feasibility of a novel high-resolution 18F-FDG PET-CT of surgical specimens of OSCC, STS and OS and compare the results to the gold standard of histopathology. Secondary Objectives:To assess the diagnostic...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON56971

Source
ToetsingOnline

Brief title
Quantitative Margin Assessment with high-resolution PET-CT

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
oral cancer, osteosarcoma, soft tissue sarcoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: intraoperative imaging, molecular imaging, nuclear medicine, surgical oncology

Outcome measures

Primary outcome

The primary aim of this study is to determine the feasibility of 18F-FDG PET-CT specimen imaging for intraoperative margin assessment in OSCC, STS and OS surgery.The feasibility is assessed by examining whether the amount of signal is sufficiënt for the PET-CT to produce a representative 3D reconstruction that allows margins to be measured at the millimeter level, corresponding to standard of care histopathological evaluation

Secondary outcome

The clinical value is measured as diagnostic performance, for which the following parameters will be will be calculated:

sensitivity (the proportion of positive final margins that are correctly identified as final positive);

specificity (the proportion of negative final margins that are correctly identified as final negative);

positive predictive value (the proportion of positive final margins that are true positive);

negative predictive value (the proportion of negative final margins that are true negative);

The results of histopathological analysis are considered as the golden standard and thus represent the *correct* margin status. Failure rate and interobserver reproducibility will also be reported by a descriptive analysis.

The standardized uptake values (SUVpeak, SUVmax) of each lymph node scanned will be correlated with metastatic status. The SUVs of benign and malignant lymph nodes will be described as as measurements of distribution: (geometric) means with standard deviation; medians with range; frequencies. To get an idea of the discriminative potential of PET-CT, a cut-off SUV value will be determined based on Youden's index.

For tumors where preoperative whole-body 18F-FDG PET-CT is available, the correlation between whole-body 18F-FDG uptake and specimen-imaging 18F-FDG uptake is studied. A Pearson correlation coefficient will be calculated.

Patient demographics (e.g. age, sex) and pathological characteristics (e.g. diagnostic status or histopathological subtype) will be presented using descriptive statistics. These will include measurements of distribution: (geometric) means with standard deviation; medians with range; frequencies. Continuous variables will be considered non-normally distributed due to the low sample size.

Study description

Background summary

The ideal outcome in oncological surgery is resection of all tumor tissue with a margin of healthy
tissue. However, positive surgical margins (PSMs) occur in up to 35% of the cases, depending on
tumor type. The final margin status is only available five to seven days after surgery so that in

case of a PSM, intensive adjuvant radiotherapy or chemotherapy is necessary. Despite adjuvant
treatment, patients still have a significantly reduced overall
survival.*Therefore, the intraoperative
identification of PSMs is paramount to enable surgical corrections and obtain a complete
resection.

Study objective

Primary objective:
To investigate the feasibility of a novel high-resolution 18F-FDG PET-CT of surgical specimens of OSCC, STS and OS and compare the results to the gold standard of histopathology.

Secondary Objectives:
To assess the diagnostic accuracy of the high-resolution mobile PET-CT, the PET-CT margin status results are compared to the results of the gold standard of histopathology. This will be quantified as diagnostic sensitivity, specificity, negative predictive value and positive predictive value.

To investigate the ability of high-resolution 18F-FDG PET-CT for intraoperative assessment of lymph node status, in case lymph node excision is performed during OSCC, STS and OS surgery. This will be quantified as diagnostic sensitivity and specificity compared to the gold standard of histopathological examination;

To compare the high-resolution 18F-FDG PET-CT specimen images with preoperative whole-body 18F-FDG PET-CT images of the same patients, if available. This comparison will provide insight into tissue uptake that is detected at different levels of spatial resolution;

To investigate possible relations between 18F-FDG tumor uptake and histopathological characteristics of the tumor;

Study design

The study is designed as follows:

Patients eligible for inclusion have biopsy-confirmed OSCC, STS or OS and are scheduled for surgical treatment.

Patients interested will be informed about the study at the outpatient clinic and in-/exclusion criteria will be checked. Patients have a maximum of one week to decide whether they participate in the study or not. This one-week interval will never delay the surgical intervention. Written informed consent will be

obtained.

On the day of surgery, 2.0 MBq/kg 18F-FDG will be adminstered at the Department of Nuclear Medicine and Molecular Imaging.

Surgery is performed according to standard of care. The perioperative personnel, as deemed necessary based on risk analysis by clinical physicist/radiation safety expert, will wear electronic dosimeters. Pregnant personnel is not allowed in the operation room as long as the patient is present. Directly after surgery, high-resolution PET-CT imaging of the surgical specimen is performed. No treatment decisions will be taken based on the images acquired by the specimen imager. Additional resected tissue (e.g. lymph nodes) could also be imaged by the high-resolution PET-CT specimen imager.

All resected specimens are sent to the Department of Pathology for standard-of-care histopathological analysis.

Intervention

Administration of 18F-FDG (0.8 MBq/kg)

Study burden and risks

Administration of the radiotracer takes place during standard care admission of the patient

The whole-body radioactive dose of the administered tracer is estimated at 1.2 mSv. In comparison, a chest X-ray has a dose of 0.4 mSv, a chest CT scan results in a dose of 6.1 mSv and a person living at sea level for a year is exposed to about 2.4 mSv of natural radiation. Therefore, the risk associated with the exposed radiation caused by the administered low-dose tracer is estimated to be low.

For hospital personnel involved in study procedure: The perioperative personnel, as deemed necessary based on risk analysis by clinical physicist/radiation safety expert, will wear electronic dosimeters. Pregnant personnel is not allowed in the operation room as long as the patient is present.

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

Age >=18 years.

Patient is confirmed with oral squamous cell carcinoma, soft tissue sarcoma or osteosarcoma.

Patient is indicated to undergo curative surgery of the primary tumor.

Patient diagnosed with STS have received neoadjuvant radiotherapy of the primary tumor.

Patient is estimated compliant for study participation by the investigator.

Written informed consent.

Exclusion criteria

Medical or psychiatric conditions that compromise the patient*s ability to give

informed consent;

Patient has participated in other clinical studies with radiation exposure of more than 1 mSv in the past 12 months;

A blood glucose level over 200 mg/dL on the day of surgery.

Patients diagnosed with OSCC and OS having received neoadjuvant radiotherapy of the primary tumor region;

Pregnancy or lactation.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2024
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	22-08-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-03-2025
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL86142.042.24