# Validation of FDG-PET segmentation tools for tumor delineation by correlation of CT- and PET volume measurements with histopathology of nodal metastases of head and neck carcinomas.

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To validate FDG-PET segmentation tools for radiation target volume definition by correlation of CT and FDG-PET volume measurements with histology of nodal metastases of squamous cell carcinoma of the head and neck.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON32216

**Source**
ToetsingOnline

**Brief title**
Validation of FDG-PET segmentation tools.

### Condition

- Other condition
- Malignant and unspecified neoplasms gastrointestinal NEC
- Respiratory tract neoplasms

**Synonym**
head and neck cancer, squamous cell carcinoma of head and neck

**Health condition**

plaveiselcelcarcinomen uitgaande van cavum oris, oropharynx, hypopharynx, larynx

**Research involving**
Human

## Sponsors and support

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

## Intervention

**Keyword:** 18F-fluorodeoxyglucose(FDG)-positron emission tomography(PET), Functional Imaging, Head and neck cancer, Radiation treatment planning

## Outcome measures

### Primary outcome

How accurate are the several FDG-PET segmentation tools in displaying the true

tumor volume?

### Secondary outcome

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# Study description

### Background summary

Progress in radiation oncology enables delivery of radiation treatment with increasing geometric precision. This requires a re-evaluation of target volume delineation. This could improve by adding information provided by a molecular imaging modality such as 18F-fluorodeoxyglucose (FDG)-positron emission tomography (PET) to the current standard computed tomography (CT). To achieve this, several FDG-PET segmentation tools have been developed based on phantom experimentents. The aim of the study is to validate the FDG-PET segmentation tools by correlation of CT and FDG-PET volume measurements with histology of nodal metastases of head and neck carcinomas.
When a greater insight in the value of the FDG-PET segmentation tools is achieved, one will be able to integrate the information provided by FDG-PET in the target volume definition with a greater certainty. This could have many advantages, such as an increased accuracy in identifying the tumor. This could

have consequences for the size and the shape of the radiation target volume.

### Study objective

To validate FDG-PET segmentation tools for radiation target volume definition by correlation of CT and FDG-PET volume measurements with histology of nodal metastases of squamous cell carcinoma of the head and neck.

### Study design

An FDG-PET/CT scan is performed prior to the already scheduled neckdissection. The volume that each FDG-PET segmentation tool identifies as 'tumor volume', will be validated by measuring the true volume during histological analysis.

### Study burden and risks

The burden for the participanting patient is limited to the performance of an FDG-PET/CT scan of the head and neck region.

## 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

•All patients with N+ squamous cell carcinoma of the head and neck, planned for neck dissection
•Age >18 years

## Exclusion criteria

•Pregnancy
•Women breast feeding

# 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): | 01-04-2008 |
| Enrollment: | 15 |
| Type: | Anticipated |

# Ethics review

Approved WMO

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|---|---|
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 | NL22554.091.08 |