# Validation of hypoxia imaging of cancer in the head and neck area with FAZA-PET

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To determine the test-retest variability of quantitative hypoxia imaging with FAZA-PET, both in untreated subjects (track A) and during radiotherapy (track B). The purpose of this study is to validate FAZA-PET as a selection criterion for...

Ethical review Approved WMO

**Status** Pending

**Health condition type** Miscellaneous and site unspecified neoplasms malignant and

unspecified

**Study type** Observational invasive

## **Summary**

### ID

NL-OMON32369

#### Source

ToetsingOnline

#### **Brief title**

FAZA-PET hypoxia imaging in head-neck cancer

## **Condition**

Miscellaneous and site unspecified neoplasms malignant and unspecified

#### Synonym

Cancer of head-neck, oropharyngeal cancer

#### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

### Intervention

**Keyword:** FAZA, Head neck cancer, Hypoxia, PET

## **Outcome measures**

## **Primary outcome**

Test-restest variability of FAZA-PET quantification (as a percentage with 95% conficence interval).

## **Secondary outcome**

Not applicable.

# **Study description**

## **Background summary**

Low oxygen levels in tumor tissue (hypoxia) is an important adverse factor in radiotherapy of head-neck tumors. Hypoxia can be visualized quantitatively with the PET-tracer fluor-18-\*uoroazomycin-arabinoside (FAZA). This makes FAZA-PET a potential instrument for selection of hypoxia-modulating strategies, that could improve the response to radiotherapy in the presence of hypoxia. Currently the normal variations in (FAZA-PET imaging of) tumor hypoxia are unknown. This hinders determination of thresholds for detection of significant hypoxia, and for detection of significant changes therein as induced by hypoxia modulation.

## **Study objective**

To determine the test-retest variability of quantitative hypoxia imaging with FAZA-PET, both in untreated subjects (track A) and during radiotherapy (track B). The purpose of this study is to validate FAZA-PET as a selection criterion for application of hypoxia-modulating strategies, and as a tool to determine the effectiveness of these strategies prior to and during radiotherapy.

## Study design

Repeated quantitative hypoxia imaging (2 times) without intevention (track A) and during radiotherapy (track B). Analysis of the test-retest variability.

#### Study burden and risks

Patient burden: 2 FAZA-PET/CT scans, with per scan: placement of an intravenous catheter, injection of 190-240 MBq F-18-FAZA (estimated 7 mSv), 15 min dynamic PET acquisition and 15 min static PET acquisition in a total time range of 2 hours. Lowdose CT for attenuation correction of the PET signal (estimated 1 mSv per acquisition), thus a total radiation burden per FAZA-PET/CT scan of about 9 mSv. This is well within the range of normal diagnostic imaging. The risk of this radiation exposure is negligible relative to the subsequent radiotherapy with curative intent.

## **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

Histology proven oropharyngeal cancer, stage III or IV, any grade, eligible for RADPLAT.

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## **Exclusion criteria**

Pregnancy

# Study design

## **Design**

Study phase: 2

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

## Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-06-2008

Enrollment: 20

Type: Anticipated

## **Ethics review**

Approved WMO

Application type: First submission

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

CCMO NL22153.031.08