# Assessment of tumor hypoxia during radiotherapy course in locally advanced Head and Neck cancer with 18Ffluoroazomycin arabinoside (18F-FAZA)-PET-CT

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To investigate for patients with locally advanced HNSCC, the dynamics of tumour hypoxia during the course of radiotherapy/chemoradiation using 18F-FAZA PET-CT. To investigate the best strategy for gradual dose escalation. This may be done by using...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

# Summary

### ID

NL-OMON36574

**Source** ToetsingOnline

**Brief title** FAZA pilot study

### Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

#### Synonym

Hypoxia in locally advanced Head and Neck cancer

### Health condition

hoofd hals kanker

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#### **Research involving**

Human

### **Sponsors and support**

Primary sponsor: Universitair Medisch Centrum Groningen Source(s) of monetary or material Support: De studie wordt gefinancieerd door []budget disciplinegroep radiotherapie[]

### Intervention

**Keyword:** 18F-fluoroazomycin arabinoside (18F-FAZA)-PET-CT, locally advanced Head and Neck cancer, radiotherapy

#### **Outcome measures**

#### **Primary outcome**

Tumour hypoxia prior and during the course of radiotherapy/chemoradiation using

18F-FAZA PET-CT for locally advanced HNSCC

#### Secondary outcome

To investigate tumour heterogeneity with 18F-FAZA PET-CT

More specifically, the following endpoints will be used:

\* SUV hypoxia prior to therapy (SUV max, SUV70%) [Research 18F-FAZA PET scan]

\* SUV hypoxia week 1 of therapy (SUV max, SUV70%) [Research 18F-FAZA PET scan]

\* SUV hypoxia week 2 of therapy (SUV max, SUV70%) [Research 18F-FAZA PET scan]

\* SUV hypoxia week 4 of therapy (SUV max, SUV70%) [Research 18F-FAZA PET

scan]

# **Study description**

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#### **Background summary**

A major cause of treatment failure of HNSCC is tumour hypoxia. Hypoxic cells are resistant to the cytotoxic effects of both chemotherapy and ionizing radiation.

A possible way to improve radiotherapy/chemoradiation results in locally advanced HNSCC is to increase the radiation dose delivered to hypoxic areas within the tumour. An image modality to visualize hypoxic areas, which can be incorporated into the treatment plan, is 18F-FAZA PET-CT. Therefore, it is hypothesized that 18F-FAZA PET-CT can be used to guide radiotherapy in order to substantially increase the dose to hypoxic tumour sub-volumes. Unfortunately, not much is known how these hypoxic sub-volumes behave during the course of the radiotherapy/chemoradiation. Therefore much more data regarding possible hypoxia changes during radiotherapy/chemoradiation is required before the radiation dose can be safely increased.

#### Study objective

To investigate for patients with locally advanced HNSCC, the dynamics of tumour hypoxia during the course of radiotherapy/chemoradiation using 18F-FAZA PET-CT.

To investigate the best strategy for gradual dose escalation. This may be done by using IMRT with a simultaneous integrated boost (SIB), intensity modulated arc therapy (IMAT), stereotactic boost (SRT) or protons.

### Study design

Observational pilot study

#### Study burden and risks

Possible hematoma and pain at the place of injection.

Extra radiationd dose: patients receive extra dose per 18F-FAZA PET-CT scan of 6 mSv. For 4 18F-FAZA PET-CT scans, this will be about 24 mSv (= 24 mGy). During the treatment, a patient will receive a total dose of 70.000 mGy curative radiation. The extra radiation dose (24 mSv = 0.04%) exposure is considered acceptable in relation to the prescribed radiation dose (70.000 MSv). In addition, it should be taken into account that the inaccuracy in the dose calculation for the radiotherapy treatment is about 3% (= 2100 mSv). This is 88 times the additional dose received from the 4 extra 18F-FAZA PET-CT scans. Besides normal side effects due to the radiotherapy/chemoradiation, no other toxicities are expected.

Duration of the 18F-FAZA PET-CT scan is 3 Hours (of which 2 hours is waiting

time). In totality this is 12 Hours Patients has to come one extra time to the hospital. The other 3 18F-FAZA PET-CT scan will take place at times patients are already in the hospital.

# Contacts

#### Public

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

\* Intended curative primary (chemo)radiation for patients with locally advanced HNSCC.

\* Age \* 18 years.

- \* WHO performance status 0-2 (see appendix 1)
- \* Histological of cytological confirmation of HNSCC
- \* Locally advanced HNSCC (stage III-IV), TNM classification [8]
- \* Staging procedure should at least include CT-neck, MRI-neck and 18F-FDG-PET-scan
- \* Life expectancy of at least 6 months

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\* Planned for 35 x 2 Gy IMRT eventually with concomitant chemotherapy

\* Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.

\* Before patient registration/randomisation, written informed consent must be given according to ICH/EU GCP, and national/local regulations.

### **Exclusion criteria**

Not fullfilling the inclusioncriteria

# Study design

### Design

Study type: Observational non invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2011
Enrollment:	20
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	04-05-2011
Application type:	First submission
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** CCMO **ID** NL34936.042.11