

# Dynamics of tumour hypoxia and metabolism during Chemoradiotherapy for stage III Non Small Cell Lung Cancer, using 18F-FAZA-PET/CT and 18F-FDG-PET/CT. A Pilot Study

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To investigate the dynamics of tumour hypoxia as assessed by 18F-FAZA PET/CT during and after chemoradiotherapy. To investigate the best strategy to deliver a boost dose to the hypoxic tumour areas. This strategy may be either a simultaneous boost (...)

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Respiratory and mediastinal neoplasms malignant and unspecified
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON39397

### Source

ToetsingOnline

### Brief title

Tumour hypoxia and tumour metabolism during Chemoradiotherapy.

### Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

### Synonym

non-small-cell-lung-cancer

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** CTMM Consortium

## Intervention

**Keyword:** Chemoradiotherapy, FAZA-PET, FDG-PET

## Outcome measures

### Primary outcome

Assessing tumour hypoxia using 18F-FAZA-PET/CT for stage III NSCLC during curative chemoradiotherapy

### Secondary outcome

To investigate tumour heterogeneity with respect to metabolism (18F-FDG-PET) and hypoxia (18F-FAZA-PET)

Correlation between 18F-FAZA-PET/CT identified tumour hypoxic areas and 18F-FDG-PET/CT metabolically active areas

To investigate metabolic response as assessed by 18F-FDG-PET/CT during treatment

To investigate hypoxia response as assessed by 18F-FAZA-PET/CT during treatment

## Study description

### Background summary

Lung cancer is the leading cause of worldwide cancer mortality. Non-small cell lung carcinoma (NSCLC) accounts for 80% of all cases, of which approximately 30% is stage III disease. Chemoradiotherapy is the cornerstone in the management of locally advanced NSCLC. Unfortunately, loco-regional control remains poor with 5-years overall survival rates of about 15-25%. An important contributor of poor local control after radiotherapy is tumour hypoxia.

This study aims to investigate the best treatment strategy to deliver high radiation dose precisely to hypoxic zones with sophisticated imaging techniques like PET/CT using specific biological tracers such as FAZA. Performing FAZA-PET/CT scans during chemoradiotherapy can give valuable information about the dynamics of tumour hypoxia during treatment thereby adjust radiotherapy treatment planning to improve local tumour control and overall survival.

### **Study objective**

To investigate the dynamics of tumour hypoxia as assessed by  $^{18}\text{F}$ -FAZA PET/CT during and after chemoradiotherapy.

To investigate the best strategy to deliver a boost dose to the hypoxic tumour areas. This strategy may be either a simultaneous boost (SIB) technique to escalate the dose to hypoxic areas, in the case of stable hypoxic areas during treatment, or a single stereotactic boost dose to the hypoxic area in the case of fluctuating hypoxic areas.

Finally, the relation between tumour hypoxia and tumour metabolism during chemoradiotherapy will be investigated.

### **Study design**

Observational pilot study

### **Study burden and risks**

Patients will receive 4 extra FAZA-PET/CT (24mSv) and 2 extra FDG-PET/CT (15.2mSv) overall patients receive 39.2mSv.

This extra radiation dose exposure is considered acceptable in relation to the prescribed radiation dose (60.000mSv).

## **Contacts**

### **Public**

Universitair Medisch Centrum Groningen

Hanzeplein 1  
Groningen 9700 RB  
NL

### **Scientific**

Universitair Medisch Centrum Groningen

Hanzeplein 1  
Groningen 9700 RB

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- WHO PS 0-2
- Histological or cytological confirmation of non-small cell lung cancer.
- Stage IIIA or IIIB
- Adequate pulmonary function estimated by flow volume curves
- Life expectancy of at least 6 months
- Planned for 25 x 2.4 Gy 3DCRT, with concomitant chemotherapy

### Exclusion criteria

- Other stages than stage III NSCLC
- PS > 2

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2011
Enrollment:	10
Type:	Actual

## Ethics review

Approved WMO	
Date:	17-12-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved	
Date:	05-11-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	24-04-2013
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	NL33218.042.10