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

Published: 17-12-2010
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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 (...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	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 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 (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

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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