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

Published: 18-09-2008
Last updated: 07-05-2024

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.

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