[11C]Erlotinib tumor heterogeneity: an in vivo study using static whole body positron emission tomography in non-small cell lung cancer patients.

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To evaluate interlesional and intralesional differences in [11C]erlotinib uptake in EGFR mutated (EGFR+) NSCLC patients who are at different stages in their TKI treatment. To correlate tumor [11C]erlotinib uptake to EGFR mutational status, tumor…

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

Summary

ID

NL-OMON44987

Source
ToetsingOnline

Brief title
[11C]erlotinib tumor heterogeneity in WB PET in patients with NSCLC

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, non-small cell lung carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: KWF

Intervention

Keyword: [11C]erlotinib, heterogeneity, non-small cell lung cancer, positron emission tomography

Outcome measures

Primary outcome

Tumor-to-blood ratio (TBR) measures of [11C]erlotinib uptake in tumors and

metastases

Correlation between TBR form different lesions and parts of tumor lesions

Secondary outcome

Correlation of tumor TBR with EGFR mutational status

Correlation of TBR in tumors and metastases with [18F]FDG standardized uptake

values (SUV)

Correlation of tumor TBR with radiologic changes under TKI therapy (using

RECIST)

Study description

Background summary

We previously labeled erlotinib, an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI), with the positron emitter C-11, and showed in a positron emission tomography (PET) study that [11C]erlotinib accumulation in non-small cell lung cancer (NSCLC) tumors could be quantified in patients both on and off erlotinib therapy. In TKI-naïve patients [11C]erlotinib was shown to be correlated with EGFR mutational status and tumor response to erlotinib therapy. However, it is well known that intralesional and interlesional EGFR expression and mutation within one patient may be different. And, this may change during TKI treatment. To study this interlesional and intralesional heterogeneity of tumor sensitivity to TKI, whole body PET scans are essential.

Study objective

To evaluate interlesional and intralesional differences in [11C]erlotinib uptake in EGFR mutated (EGFR+) NSCLC patients who are at different stages in their TKI treatment. To correlate tumor [11C]erlotinib uptake to EGFR mutational status, tumor metabolic activity (using [18F]FDG PET) and radiologic tumor response to TKI therapy.

Study design

An observational study.

Study burden and risks

A venous cannula will be inserted. The total amount of blood withdrawn will be no more than 21 mL (3x7mL) and 42 mL (6x7mL) in patients without and with erlotinib therapy, respectively. The total amount of radiation burden (form CT thorax and PET scan together) will be approximately 5 mSv. The overall procedure time will be approximately 1.5 hours.

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

- Three groups of 10 evaluable patients, i.e. 30 evaluable patients, with histologically proven NSCLC, with an activating EGFR mutation as assessed by HRM and DNA-sequencing;- Three groups are:;1. Patients who were never treated with TKI, planned to receive TKI therapy. ;2. Patients who relapse under TKI therapy, planned to stop TKI therapy;3. Patients who relapsed after second line cytotoxic chemotherapy and are planned for TKI retreatment. ;- Age between 18 and 70 years;- Life expectancy of at least 12 weeks;- Malignant lesions (at least 2) of at least 1.5 cm diameter as measured by CT ;- Karnofsky index ><=60%;- Written informed consent

Exclusion criteria

- Claustrophobia;- Pregnant or lactating patients;- Concurrent treatment with experimental drugs

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[11C]erlotinib
Generic name:	[11C]erlotinib

Ethics review

Approved WMO Date:	16-11-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-05-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2015-001518-86-NL
CCMO	NL53111.029.15