[11C]Erlotinib pharmacokinetics: an in vivo study using positron emission tomography in non-small cell lung cancer patients with and without erlotinib therapy.

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To compare tumor [11C]erlotinib pharmacokinetics in NSCLC patients with and without erlotinib therapy. Also, to assess the relationship of venous sampling versus arterial, of tumor [11C]erlotinib uptake and blood flow with and without therapy, and...

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

Summary

ID

NL-OMON36826

Source
ToetsingOnline

Brief title
[11C]erlotinib kinetics in NSCLC with and without erlotinib

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, non-small cell lung cancer, pharmacokinetics, positron emission tomography

Outcome measures

Primary outcome

1) [11C]erlotinib pharmacokinetics with and without erlotinib therapy,

Secondary outcome

2) comparison of venous versus arterial sampling for correcting pharmacokinetic

input curves,

3) relationship between [11C]erlotinib pharmacokinetics in tumor tissue and

tumor blood flow with and without erlotinib therapy,

4) assessing the correlation between uptake parameters from dynamic PET scans

and static whole body scans, obtained by reconstructing the available dynamic

PET data.

5) Validate IDIF against continuous arterial sampling.

Study description

Background summary

We previously labeled erlotinib, an EGFR TKI, with the positron emitter C-11, and showed in a positron emission tomography (PET) study that [11C]erlotinib accumulation in TKI-naïve non-small cell lung cancer (NSCLC) tumors could be quantified. [11C]erlotinib was shown to be correlate with EGFR mutational status and tumor response to erlotinib therapy. To use this technique in patients who are being treated with erlotinib, but may be developing

progression, we need to validate the previous results in patients with and without erlotinib therapy.

Study objective

To compare tumor [11C]erlotinib pharmacokinetics in NSCLC patients with and without erlotinib therapy. Also, to assess the relationship of venous sampling versus arterial, of tumor [11C]erlotinib uptake and blood flow with and without therapy, and to explore the usefulness of static whole body images. Also, to validate image derived input function (IDIF) against continuous arterial sampling.

Study design

An observational study with invasive measurements.

Intervention

The procedure consists of a low dose CT scan, intravenous administration of [15O]H2O and 15-minutes [15O]H2O PET scan, followed by another low dose CT scan, intravenous administration of [11C]erlotinib and PET acquisition for about one hour with arterial and venous blood sampling during [11C]erlotinib PET scanning. The first 2 patients will also undergo continuous arterial sampling during [11C]erlotinib PET. To compare tumor [11C]erlotinib uptake with and without erlotinib therapy, this scanning sequence will be performed prior to therapy and 1 week after start of therapy. A tumor biopsy will be taken before PET scanning.

Study burden and risks

The total amount of blood withdrawn will be no more than 270 mL for the first 2 patients and no more than 200 mL (7mLx7x2x2) for the rest of the patients, including both test and retest procedures. The total amount of radiation burden: 7 mSv.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL
Scientific

Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with NSCLC, planned to receive erlotinib for therapy will be included in this study.
Patients age: between 18 and 70 years
Life expectancy of at least 12 weeks
Malignant lesion of at least 1.5 cm diameter within the chest as measured by CT
Performance status Karnofsky index >60%
Written informed consent

Exclusion criteria

Claustrophobia
Pregnant or lactating patients
Metal implants in the thorax (e.g. pacemakers), interfering with PET/CT imaging
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):	07-10-2013
Enrollment:	10
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	12-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-02-2013
Application type:	First submission
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	EUCTR2012-004475-39-NL
CCMO	NL41138.029.12