FLT PET in patienten met niet kleincellig long carcinoom behandeld met gefitinib.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24060

Source
Nationaal Trial Register

Health condition

NSCLC

Sponsors and support

Primary sponsor: VU University Medical Center (VUmc) Amsterdam
Source(s) of monetary or material Support: IMI

Intervention

Outcome measures

Primary outcome

The study parameters are the results of the simplified measures and the pharmacokinetic modeling of [18F]FLT PET prior to therapy and during treatment with gefitinib.

Secondary outcome

Secondary, nonlinear kinetic filtering will be evaluated and perfusion measured with [15O]H2O PET.

Study description

Background summary

The aim of the present study is to validate simplified quantitative methods for [18F]FLT PET in patients with non-small cell lung cancer (NSCLC) treated with gefitinib.

It is monocenter, prospective observational study including 10 patients with NSCLC who will be scanned with [15O]H2O and [18F]FLT PET on three separate occasions: within 7 days prior to treatment, and 7 and 28 days after the first therapeutic dose of gefitinib, respectively. Full kinetic analysis will be performed.

Study objective

Simplified FLT PET parameter.

Study design

Baseline, and 7 and 28 days after start of treatment.

Intervention

[15O]H2O and [18F]FLT PET scan at 3 different timepoints.

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Eligibility criteria

Inclusion criteria

1. Patient age 18 years or older;

2. Histological diagnosis of NSCLC;

3. Active EGFR-TK mutation;

4. Scheduled for treatment with gefitinib;

5. Tumour diameter > 3cm (to minimize partial volume effects) within the chest;

6. Able to remain supine for 90 minutes in the PET-CT scanner;

7. Written informed consent.

Exclusion criteria

1. Pregnant or lactating patients;

2. Metal implants (e.g. pacemakers);

3. Body weight > 100 kg.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2012

Enrollment:	10
Type:	Actual

Ethics review

Positive opinion Date:	02-08-2012
Application type:	First submission

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
NTR-new	NL3386
NTR-old	NTR3557
Other	METc VUmc : 12/172
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A