Adherence and patients’ experiences with erlotinib.

No registrations found.

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

Summary

ID

NL-OMON26332

Source
Nationaal Trial Register

Brief title
Caper

Health condition

Cancer
Oral chemotherapy
Erlotinib
Adherence
Plasma concentration

Longkanker
Orale chemotherapie
Erlotinib
Therapietrouw
Plasmaconcentratie

Sponsors and support

Primary sponsor: VU medical centre, Amsterdam
Source(s) of monetary or material Support: Roche Nederland B.V.

Intervention

Outcome measures

Primary outcome

1. Adherence rate; a patient is adherent with the intake of 85% or more of the prescribed medication;

2. Plasma concentration of erlotinib;

3. Number and grade of side-effects.

Secondary outcome

1. Quality of life;

2. Attitude towards disease;

3. Beliefs and attitude towards medicines;

4. Percentage of dose adjustment;

5. Discontinuation.

Study description

Background summary

Background of the study:

Adherence to treatment is a complex and multifaceted issue that can substantially alter the outcomes of therapy. Variation in plasma concentration may be due to variability in pharmacokinetics. Even in a clinical trial setting there is a considerable variability in efficacy and side effects of erlotinib. In a less controlled environment, like the use of erlotinib in daily practice, adherence may also play a significant role. Only few studies have focused on the use of oral anticancer drugs in daily practice and the influence of adherence to its effectiveness. Information about the reasons for non-adherence among non-small-cell-lung cancer (NSCLC) patients taking the oral anticancer drug erlotinib is essential for the development of interventions that may increase adherence.

Objectives of the study:

Primary Objective: To study the relationship between adherence and the plasma concentration of erlotinib and to study the relationship between side effects and adherence to erlotinib in patients with NSCLC.

Secondary Objective: The second part of this study is of an explorative nature. The relationships between patient characteristics, disease characteristics, side effects, quality of life, patients beliefs and attitude towards disease and medicines, adherence, dose adjustments and plasma concentration of erlotinib in patients with NSCLC will be studied.

Study design/methods:

Prospective observational cohort study in which 50 patients starting with treatment with erlotinib will be followed up until 16 weeks. NSCLC patients of 18 years or older under treatment in one of the participating hospitals in the Netherlands starting with erlotinib can be included. Before the start of therapy with erlotinib and during week 3-4, 8-9, 12 and 15-16, patients will be asked to fill in a questionnaire. Furthermore in week 3-4, 8-9 and 15-16 blood samples are collected, which will be analysed for plasma concentration of erlotinib. Adherence will also be measured using an medication event monitoring system (MEMS).

Study objective

The present study aims to get more insight into the various aspects that govern adherence to the oral anticancer drug erlotinib in daily practice.

Study design

Baseline and [3 or 4], [8 or 9], [12] and [15 or 16] weeks after baseline.

Intervention

None, this is an observational study.
The use of erlotinib in daily practice will be monitored for 4 months.

Contacts

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Eligibility criteria

Inclusion criteria

NSCLC patients starting with erlotinib.

Exclusion criteria

Younger than 18 year or insufficient knowledge of the Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2009
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	25-05-2009
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	NL1720
NTR-old	NTR1830
Other	VUmc, KFA : OZ05KFA00002
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A