Adherence and patients' experiences with the use of erlotinib in NSCLC treatment: The influence on plasma concentration and the exploration of factors affecting the use in daily practice

Published: 19-05-2009
Last updated: 04-05-2024

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 study is partly of...

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

Summary

ID

NL-OMON33122

Source
ToetsingOnline

Brief title
Adherence and patients* experiences with erlotinib

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
non-small-cell-lung cancer or lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Roche Nederland B.V.

Intervention

Keyword: Adherence, Erlotinib, Oral chemotherapy, Plasma concentration

Outcome measures

Primary outcome

Adherence rate; a patient is adherent with the intake of 85% or more of the

prescribed medication, the plasma concentration of erlotinib and the number and

grade of side-effects.

Secondary outcome

Quality of life

Attitude towards disease

Beliefs and attitude towards medicines

Percentage of dose adjustment and discontinuation

Study description

Background summary

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.

Study objective

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 study is partly 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

Prospective observational cohort study in which 50 patients starting with treatment with erlotinib will be followed up until 16 weeks.

Study burden and risks

Before the start of therapy with erlotinib and during week 2, 4, 8, 12 and 16 patients will be asked to fill in a questionnaire. Furthermore in week 4, 8 and 16 blood samples are collected, which will be analysed for plasma concentration of erlotinib.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
1081 HV Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

NSCLC patients starting with erlotinib

Exclusion criteria

younger than 18 year

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-10-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2010
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
CCMO	NL27629.029.09