A MULTICENTER, RANDOMIZED, DOUBLE BLIND, CONTROLLED PHASE 3, EFFICACY AND SAFETY STUDY OF SUNITINIB (SU011248) IN PATIENTS WITH ADVANCED/METASTATIC NON SMALL CELL LUNG CANCER TREATED WITH ERLOTINIB

Published: 22-06-2007
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The purpose of this clinical trial is to test whether treatment of patients with NSCLC with erlotinib plus sunitinib is better than treatment with erlotinib plus placebo. All patients enrolling in this study will receive treatment with erlotinib.

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

Summary

ID

NL-OMON33771

Source
ToetsingOnline

Brief title
A6181087

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, non-small cell lung cancer (NSCLC)

Research involving
Human

Sponsors and support

Primary sponsor: Pfizer
Source(s) of monetary or material Support: Pfizer

Intervention

Keyword: double-blind, erlotinib, non-small cell lung cancer, sunitinib

Outcome measures

Primary outcome

Overall Survival

Secondary outcome

Progression-Free Survival

Objective Response Rate

One-year Survival

Duration of Response

Type, incidence, severity, timing, seriousness, and relationship to study

therapy of adverse events; laboratory abnormalities

Patient-reported outcomes as measured by the EQ-5D questionnaire

Study description

Background summary

Erlotinib is used to treat patients with advanced or metastatic NSCLC after failure of one or two prior chemotherapy regimens. Erlotinib is an Epidermal Growth Factor Receptor (EGFR) inhibitor - it blocks the signal that EGFR sends to the cancer cells to make them grow.

Sunitinib is approved by the US FDA for the treatment of Gastrointestinal

Stromal Tumor - a rare type of gastrointestinal cancer - and for the treatment of advanced kidney cancer. Sunitinib is an investigational agent in NSCLC that is thought to work by killing cancer cells and slowing tumor growth and the growth of new blood vessels that supply nutrients to tumors. Sunitinib does this by blocking molecules on the surface of cancer cells and the surrounding blood vessels that send the signals to grow. To date, over 7000 patients with advanced cancer have been treated with sunitinib. Studies in patients with NSCLC are in early stages and have not yet proven that sunitinib is effective in this disease; however, a few patients with NSCLC who were treated with sunitinib have shown tumor responses to treatment.

Study objective

The purpose of this clinical trial is to test whether treatment of patients with NSCLC with erlotinib plus sunitinib is better than treatment with erlotinib plus placebo. All patients enrolling in this study will receive treatment with erlotinib.

Study design

This study is a multinational, multicenter, randomized, double-blind, controlled, phase 3 efficacy and safety study of sunitinib combined with erlotinib versus placebo combined with erlotinib in patients with advanced/metastatic non-small cell lung cancer.
Treatment on study will be administered in 4-week cycles. The starting dose of erlotinib will be 150 mg daily administered orally and of sunitinib 37,5 mg daily administered orally. The dosage may be elevated or reduced based on tolerability by the investigator.
Disease progression and overall survival will be assessed in all patients who will be followed until death.

Intervention

erlotinib: All patients will receive erlotinib. Erlotinib tablets will be taken every day by mouth at a starting dose 150 mg continuously.

Sunitinib: capsules of sunitinib at 37.5 mg or placebo once daily continuously.

The study doctor might change the dosage if in his opinion it would be better.

Study burden and risks

number of blooddraws: 16 x
number of physical examinations: 13 x
number of questionnaires: 14 x
number of CT/MRI: 7 x

number of bone scans: 1 x
number of brainscans: 1 x

The most common adverse events of sunitinib are: diarrhea, nausea, upset stomach, taste disturbances, inflammation of mucous membranes, vomiting, constipation etc. (see patient information)

The most common side effects are rash and diarrhea (see patient information)

Risk of Blood Drawing: a risk of bruising, pain, or infection at the site of the blood draw.

Radiation Risks from Imaging Studies: The amount of radiation exposure you may receive from these standard diagnostic tests is considered small, and will not adversely affect the treatment of your disease.

Contrast dye for CT scans: hives and itching or other allergic symptoms

MRI scans: Because of a strong magnetic field metal prostheses or pace makers might malfunction

Contacts

Public
Pfizer

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NL
Scientific
Pfizer

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2909 LD Capelle a/d IJssel
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Histologically or cytologically proven diagnosis of NSCLC with evidence of disease that is recurrent and for which erlotinib treatment is clinically indicated;Prior treatment with 1 or 2 chemotherapy regimens ;Disease progression during or after first-line chemotherapy

Exclusion criteria

Prior treatment with any receptor tyrosine kinase inhibitors, VEGF inhibitors, or other angiogenesis inhibitors;Treatment with sunitinib and/or erlotinib if it is contraindicated according to the local prescribing information

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2007
Enrollment:	100

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Sutent
Generic name:	sunitinib
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Tarceva
Generic name:	erlotinib
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	22-06-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-08-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-11-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-11-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-12-2007

Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-03-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-03-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-06-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-06-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	16-06-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-06-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-08-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	01-10-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-10-2008
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-03-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-04-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-07-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	12-08-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-10-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-10-2010
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-10-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	EUCTR2007-001915-52-NL
ClinicalTrials.gov	NCT00457392
CCMO	NL17998.068.07