Treatment with BIBF1120 capsules lung carcinoma patients with an abnormal fibroblast growth factor-1 receptor (NVALT15)

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28108

Source
NTR

Brief title
NVALT15

Health condition

Non-small cell lung cancer (NSCLC).

Sponsors and support

Primary sponsor: Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose NVALT (dutch society of pulmonary physicians)
Source(s) of monetary or material Support: NVALT

Intervention

Outcome measures

Primary outcome

Progression free survival.

Secondary outcome

Response rate, duration of response, overall survival, safety and tolerability.

Study description

Background summary

BIBF1120 is a potent oral inhibitor of FGFR 1 and 3. This is a multicenter two-country non-comparative phase II study in 76 patients with stage IIIB or IV after failure of first line treatment or recurrent squamous and large cell lung cancer with FGFR1 amplification. Age 18 years and above. Treatment with BIBF1120. We hypothesize that these patients will show an improved progression free survival to BIBF1120.

Study objective

Second line treatment with BIBF1120 will have a positive effect on progression free survival (PFS) of lung cancer patients with an FGFR1 gene amplified in their tumor cells.

Study design

Continuously.

Intervention

Treatment with BIBF1120.

Contacts

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Eligibility criteria

Inclusion criteria

• Stage IIIB or IV after failure of first line treatment or recurrent NSCLC haboring a positive FISH for FGFR1 amplification.

• Age ≥ 18 years.

• Measurable disease

• ECOG Performance Status of 0 – 1.

• Life expectancy > 3 months.

Exclusion criteria

• Other investigational drugs or treatment in another clinical trial within the past 4 weeks.

• Chemo-, hormone-, immunotherapy or therapy with monoclonal antibodies or small tyrosine kinase inhibitors within the past 4 weeks.

• Radiotherapy on the target lesions within the last 4 weeks.

• Previous therapy with other VEGFR inhibitors or VEGF ligand inhibitors for treatment of NSCLC.

• Symptomatic brain metastases or leptomeningeal disease.

• Radiographic evidence of cavitation or necrotic tumors.

• Centrally located tumors with radiographic evidence of local invasion of major blood vessels.

• History of clinically significant haemoptysis within the past 3 months.

• Known inherited predisposition to bleeding or thrombosis.

• Pre-existing ascites and/or clinically significant pleural effusion.

• 21. Patients who are sexually active and unwilling to use a medically acceptable method of contraception..

• Pregnancy or lactation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-05-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44999

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4374
NTR-old	NTR4588
CCMO	NL46603.042.14
OMON	NL-OMON44999

Study results

Summary results
None