

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

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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28108

Bron

Nationaal Trial Register

Verkorte titel

NVALT15

Aandoening

Non-small cell lung cancer (NSCLC).

Ondersteuning

Primaire sponsor: Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose
NVALT (dutch society of pulmonary physicians)

Overige ondersteuning: NVALT

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Progression free survival.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Continuously.

Onderzoeksproduct en/of interventie

Treatment with BIBF1120.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Stage IIIB or IV after failure of first line treatment or recurrent NSCLC harboring a positive FISH for FGFR1 amplification.
- Age $\geq$ 18 years.
- Measurable disease
- ECOG Performance Status of 0 – 1.
- Life expectancy > 3 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	09-05-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44999

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

None