LUME-Lung 3. A Phase I/II study of continuous oral treatment with BIBF 1120 added to standard gemcitabine/cisplatin therapy in first line NSCLC patients with squamous cell histology.

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Run-in phase I: To confirm the safety and tolerability of BIBF 1120 up to a dose level of 200 mg b.i.d added to a standard dose of cisplatin/gemcitabine in first line NSCLC patients with squamous cell histology. Pharmacokinetics of BIBF 1120 and...

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

Summary

ID

NL-OMON39315

Source
ToetsingOnline

Brief title
LUME-Lung 3

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms

Synonym
bronchial carcinoma, non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Industrie: Boehringer Ingelheim bv

Intervention

Keyword: angiogenesis, BIBF 1120, lung cancer, maximum tolerated dose

Outcome measures

Primary outcome

Run-in phase I: dose-limiting toxicities

Phase II: progression-free survival

Secondary outcome

Run-in phase I: pharmacokinetics

Phase II: overall survival, objective response, duration of objective response,

time-to-progression, time-to-treatment failure, disease control and duration of

disease control.

Study description

Background summary

Non-small cell lung cancer (NSCLC) is the leading cause of cancer death globally with an estimated one million new cases diagnosed and 880,000 deaths in the US each year. Histological subtypes of NSCLC respond differently to chemotherapy treatment. NSCLC with squamous histology tended to have a better response in a study where the antiangiogenic drug thalidomide was added to chemotherapy. BIBF 1120 is an antiangiogenic drug in development in NSCLC and

ovarium carcinoma and has shown good tolerability. In this study, the efficacy of addition of this investigational product to standard chemotherapy (gemcitabine/cisplatin) is investigated.
As BIBF 1120 has never been tested with this chemotherapy combination, a run-in phase I will be conducted to confirm safety and tolerability of doses of up to 200 mg BIBF 1120 b.i.d.
The thalidomide study seemed to indicate that the potential benefit was largely seen in those patients who responded well to earlier treatments. Therefore, in phase 2 of the LUME-Lung 3 study, BIBF 1120 will only be administered to patients showing at least stable disease after 2 cycles of standard chemotherapy.

Study objective

Run-in phase I: To confirm the safety and tolerability of BIBF 1120 up to a dose level of 200 mg b.i.d added to a standard dose of cisplatin/gemcitabine in first line NSCLC patients with squamous cell histology. Pharmacokinetics of BIBF 1120 and clinically relevant metabolites, gemcitabine and cisplatin.

Phase II: To investigate the efficacy and safety of BIBF 1120 compared to placebo in first line NSCLC patients with squamous cell histology, and at least stable disease after two cycles of cisplatin/gemcitabine chemotherapy.

Study design

Run-in phase I: Open-label, dose-confirmation study

Phase II: Two arm randomised placebo-controlled study of continuous BIBF 1120 added to cisplatin/gemcitabine. Patients who have had at least stable disease after two cycles of cisplatin/gemcitabine treatment alone will be given up to 4 further cycles of cisplatin/gemcitabine chemotherapy with added BIBF 1120/placebo. After a total of 4 - 6 cycles of cisplatin/gemcitabine patients will continue to receive BIBF 1120/placebo monotherapy as maintenance treatment until disease progression, toxicity or withdrawal of consent.

Intervention

Addition of BIBF 1120 to standard chemotherapy regimen with cisplatin/gemcitabine, potentially followed by BIBF 1120 monotherapy.

Study burden and risks

This study investigates the addition of BIBF 1120 to standard chemotherapy. The subjects have NSCLC with squamous histology, a diasese that is difficult to treat and has limited options for therapy. BIBF 1120 has a favorable toxicity profile and can potentially enhave survival of these patients.

The patient would undergo a number of the procedures required for this study (blood draw, vital signs, CT scans) if he/she would receive chemotherapy, regardless of study participation.
In phase I of this study, blood is drawn for pharmacokinetics. A financial compensation is given, as this is an additional procedure and the subject has to stay in the hospital for up to 8 hours.
In phase II of this study, blood may be drawn (about 10 ml) for retrospective pharmacogenetic analysis. The subject can refuse participation in this testing, but may continue to participate in the main study.

Contacts

Public
Boehringer Ingelheim

Comeniusstraat 6
Alkmaar 1817 MS
NL
Scientific
Boehringer Ingelheim

Comeniusstraat 6
Alkmaar 1817 MS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Diagnosis of stage IIIB/IV or recurrent NSCLC with squamous histology

- Measurable disease according to RECIST 1.1
- ECOG score 0-1
- For phase 2: radiologically confirmed at least stable disease after 2 prior cycles of cisplatin/gemcitabine chemotherapy

Exclusion criteria

- Prior therapy for advanced, metastatic, or recurrent NSCLC. Prior neoadjuvant and/or adjuvant therapy is allowed if at least 12 months have elapsed between the end of the treatment and randomization
- Prior treatment with other VEGFR inhibitors (other than bevacizumab)
- Known pre-existent interstitial lung disease
- Active brain metastases
- Recent radiotherapy

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	nog niet bekend
Generic name:	nintedanib
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	not applicable
Generic name:	cisplatin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	not applicable
Generic name:	gemcitabine

Ethics review

Approved WMO Date:	04-01-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-09-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-12-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-02-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-05-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-08-2012

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-08-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-09-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-09-2013
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
EudraCT	EUCTR2010-019707-32-NL
CCMO	NL34616.029.10