

The real-world effectiveness and safety of anlotinib (AL3818) treatment for advanced non-small cell lung cancer

Submission date 19/01/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/01/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/08/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Non-small cell lung cancer (NSCLC) accounts for 83% of all lung cancer. Anlotinib is now the standard drug treatment for patients with advanced NSCLC where chemotherapy has failed. However, not all patients with advanced NSCLC can tolerate or are willing to receive chemotherapy in the first place. Similarly, the effectiveness of chemotherapy alone is limited. This study aims to collect patient data to evaluate the potential effectiveness and safety of anlotinib either alone or combined with additional drugs for treating NSCLC. The goal is to provide an option for patients with advanced NSCLC who are not suitable for chemotherapy and provide evidence of the combination of anlotinib with other treatments. The study's findings should help to improve the treatment of patients with advanced lung cancer.

Who can participate?

Adults over the age of 18 who are diagnosed with advanced NSCLC and receive anlotinib treatment

What does the study involve?

The investigators will review the electronic records of Peking University Shenzhen Hospital and screen the participants' data. Participants will be retrospectively allocated to one of two cohorts: those who received anlotinib treatment in the first place and those who received the treatment after other treatments failed. The study lasts 6 months in total.

What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part, but there should be benefits to the future treatment of advanced NSCLC because the results of the study are likely to influence how the physicians decide the treatment strategy. The main risk is that participants' information could get released into public view. To protect patient information, the researchers will minimize patient identifiers by assigning each participant with a unique code. All data generated in the study will be stored in the hospital with the unique code; the list of the unique codes will be maintained on secure servers, accessible to key research personnel only.

Where is the study run from?
Peking University Shenzhen Hospital (China)

When is the study starting and how long is it expected to run for?
January 2020 to September 2020

Who is funding the study?
1. Special Funding for Clinical Scientific Research of Wu Jieping Medical Foundation (China)
2. Shenzhen Sanming Project (China)
3. Shenzhen Science and Technology Innovation Commission Project (China)

Who is the main contact?
Dr Fen Wang
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ChiCTR2000032265

Study information

Scientific Title

The efficacy and safety of anlotinib (AL3818) treatment in patients with advanced non-small cell lung cancer in the real world

Study objectives

AL3818 (anlotinib) is a multi-targeted tyrosine kinase inhibitor mainly blocking vascular endothelial growth factor signaling pathway and has been approved by the National Medical Products Administration of China for ≥ 3 rd line treatment of advanced NSCLC. Despite the lack of evidence of frontline treatment, AL3818 may be preferred in clinical practice for patients with advanced NSCLC who are unsuitable or unwilling to receive standard care. The synergism between anti-angiogenesis and chemotherapy, targeted therapy, and immunotherapy validated by more and more preclinical and clinical evidence additionally provides the rationale for a combined strategy with these regimens. Furthermore, oral AL3818 therapy during the COVID-19 pandemic has irreplaceable advantages. Therefore, the researchers propose a scientific hypothesis that the front-line or combined use of AL3818 is effective in the treatment of advanced NSCLC.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/29/2020, China Ethics Committee of Registering Clinical Trials (Chinese Clinical Trial Registry Hong Kong Center, Hong Kong Baptist University Road, Hong Kong SAR, China; +86 (0)18980604562; chictr@vip.qq.com), ref: ChiCTR2000032265

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Advanced non-small cell lung cancer

Interventions

Patients with stage IIIB to IV or recurrent NSCLC who received AL3818 or AL3818-containing regimens between 01/06/2018 to 30/09/2020 are enrolled in the study. AL3818 is administered

orally once daily on day 1 to day 14 of a 21-day cycle and is continued until tumor progression, death, or unacceptable toxicity. Tumor responses are assessed by both radiologists and oncologists every 6 to 12 weeks or significant progression occurred or necessary.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

AL3818

Primary outcome measure

Progression-free survival (PFS), defined as the time from the first administration to the documented disease progression or death due to any cause, data collected from the electronic medical system of Peking University Shenzhen Hospital, assessed every 6 to 12 weeks

Secondary outcome measures

Data collected from the electronic medical system of Peking University Shenzhen Hospital, assessed every 6 to 12 weeks:

1. Objective response rate (ORR), defined as the percentage of patients with at least one confirmed response before any evidence of progression
2. Disease control rate (DCR), defined as the percentage of patients with at least one confirmed response plus stable disease before any evidence of progression
3. Overall survival (OS), defined as the time from the first administration to death from any cause or last follow-up
4. Toxicity, as categorized and graded according to the NCI-CTCAE

Overall study start date

01/01/2020

Completion date

30/09/2020

Eligibility**Key inclusion criteria**

1. Age ≥ 8 years
2. Pathologically confirmed stage IIIB/IV or recurrent NSCLC
3. Had at least one radiologically measurable disease as assessed using Response Evaluation Criteria in Solid Tumours (RECIST, version 1.1); and they did not receive local treatment such as radiotherapy or interventional therapy for the target lesions during anlotinib treatment

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Total final enrolment

203

Key exclusion criteria

1. Other pathological types than NSCLC including small cell lung cancer (including mixed with small cell and non-small cell lung cancer)
2. Patients who are diagnosed with malignancies other than NSCLC within the previous 5 years (except those with negligible risk of metastases or death and treated with curative intent, based on primary investigator discretion)

Date of first enrolment

20/04/2020

Date of final enrolment

30/09/2020

Locations**Countries of recruitment**

China

Study participating centre

Peking University Shenzhen Hospital

No.1120 Lianhua Road

Futian District

Shenzhen

China

518036

Sponsor information**Organisation**

Peking University Shenzhen Hospital

Sponsor details

No. 1120 Lianhua Road

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pkuszh_oncology@163.com

Sponsor type

Hospital/treatment centre

Website

<https://www.pkuszh.com>

ROR

<https://ror.org/03kkjyb15>

Funder(s)

Funder type

Research organisation

Funder Name

Special Funding for Clinical Scientific Research of Wu Jieping Medical Foundation
(320.6750.19088-10)

Funder Name

Shenzhen Sanming Project (SZSM201612041)

Funder Name

Science, Technology and Innovation Commission of Shenzhen Municipality
(GJHZ20180420180754917 and ZDSYS20190902092855097)

Alternative Name(s)

Shenzhen Science and Technology Innovation Commission, Shenzhen Science and Technology
Innovation Committee,

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

China

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/03/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Fen Wang (fina_wang@163.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			04/02/2021	No	No
Results article		06/08/2021	09/08/2021	Yes	No