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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

Registration date
26/01/2021

Overall study status
Completed

Last Edited
09/08/2021

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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 ≥3rd 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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
Peking University Shenzhen Hospital

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

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?
Results article		06/08/2021	09/08/2021	Yes	No
Protocol file			04/02/2021	No	No