ISRCTN14796973 https://doi.org/10.1186/ISRCTN14796973

Clinical effectiveness and side effects of different treatment methods for lung cancer

Submission date	Recruitment status	[_] Prospectively registered
11/10/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/10/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2023	Cancer	

Plain English summary of protocol
Background and study aims
The aim of this study is to assess the clinical effectiveness and side effects of different treatments for lung adenocarcinoma (the most common type of lung cancer).

Who can participate?
Late-stage lung adenocarcinoma patients admitted to the oncology department

What does the study involve?
Patients are separated into four different groups according to their gene mutation status. The four groups are treated with targeted drugs or targeted drugs combined with chemotherapy. The difference in recent treatment effects and the occurrence of adverse reactions in the seven groups are compared. Every chemotherapy cycle lasts 3 weeks. Four to six cycles are given depending on the patient's recovery and tolerance. Patients stopped taking the medication when they could not tolerate the side effects or the disease progressed.

What are the possible benefits and risks of participating?
The patients are treated professionally for their disease. There are no risks of participating.

Where is the study run from?
Fujian Provincial Hospital (China)

When is the study starting and how long is it expected to run for?
January 2017 to October 2020

Who is funding the study?
Tianqing Medical Science Development Fundl (China)

Who is the main contact?
Ting Li, fjslzjp@163.com

Contact information

Type(s)
Public

Contact name
Dr Ting Li

Contact details
Department of Oncology
Shengli Clinical Medical College of Fujian Medical University
Fujian Provincial Hospital
Fuzhou
China
350001
+86 (0)15711393692
fjslzjp@sina.com

Additional identifiers

Study information

Scientific Title
Observation on the clinical efficacy and side effects of EGFR-TKI ± chemotherapy in the treatment of EGFR mutation-positive advanced lung adenocarcinoma

Study objectives
To assess the clinical efficacy and side effects of epidermal growth factor receptor tyrosine kinase inhibitors (EGFR-TKIs) with or without chemotherapy in the treatment of EGFR mutation-positive advanced lung adenocarcinoma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2021, Fujian Provincial Hospital Ethics Committee (Shengli Clinical Medical College of Fujian Medical University, Fujian Provincial Hospital, No.134 East Street, Fuzhou, Fujian 350001, China; +86 (0)591 87557768; fjslec@163.com), ref: NUMBER/ID:K2021-11-010

Primary study design
Observational

Study design
Single-center observational cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
EGFR mutation-positive advanced lung adenocarcinoma

Interventions

103 EGFR mutation-positive stage IIIB or IV lung adenocarcinoma patients were enrolled in the department of oncology of Fujian Provincial Hospital from January 2017 to October 2020. According to gene mutation status, 103 EGFR-sensitive mutation patients were separated into four different groups: 19del alone, 19del combined with TP53 or other co-mutations, L858R alone, and L858R mutation combined with TP53 or other co-mutations. The four groups were respectively treated with targeted drugs or targeted drugs combined with chemotherapy. In the 19del alone group only targeted drugs were used and no chemotherapy was applied. The difference in recent treatment effects and the occurrence of adverse reactions in the seven groups were compared. Chemotherapy regimen: pemetrexed disodium 500 mg/ m2D1 cisplatin 25 mg/ m2D1-3 or carboplatin AUC5 were given intravenously. Every chemotherapy cycle lasted 3 weeks. Four to six cycles were given depending on the patient's recovery and tolerance. Targeted drug therapy: oral gefitinib tablets (Iressa, national drug approval J20180014, AstraZeneca Pharmaceutical Co., Ltd) 250 mg/day, once a day, patients took it orally until the end of follow-up. Patients stopped taking the medication when they could not tolerate the side effects or the disease progressed.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Pemetrexed disodium, cisplatin, carboplatin, gefitinib

Primary outcome(s)
1. Long-term efficacy: tumor progression-free survival (PFS) and survival calculated from enrollment to 1-year and 3-year follow-up
2. Adverse effects: the occurrence and severity of adverse events, including acute central nervous system adverse reactions, acute radiation pneumonia, vomiting, nausea, rash, diarrhea, liver function damage, and bone marrow suppression, using the commonly used term evaluation criterion (CTCAE4.0) of the National Cancer Center of Adverse Events and the tumor radiotherapy group (RTOG) classification standard. Calculated at 1-year and 3-year follow-up

Key secondary outcome(s)
1. Size and metastasis of the target tumor determined using head MRI, chest and abdomen CT (including adrenal gland), bone X-ray or MRI, or whole body PET-CT and other examinations before treatment and 12 weeks after treatment
2. Short-term efficacy: According to the WHO criteria for evaluation of solid tumor efficacy (RECIST1.1), patients were separated into progressive response (PD), stable response (SD), partial response (PR) and complete response (CR) groups. CR: indicated that all lymph nodes had shrunk to less than 10 mm and all visible lesions were cleared and maintained for at least a month; PR: the sum of the maximum diameters of all target tumors was reduced by more than 30% from baseline and remained stable for at least a month; PD: signifies that there is more than 20% growth in the sum of all target tumor maximum diameters from the minimum, and there are at least 5 mm increases in the absolute value of the maximum diameters, or that one or more new lesions emerge; SD stands for the status between PR and PD. ORR= (CR+PR)/total number of cases ×100%.

Completion date
01/10/2020

Eligibility

Key inclusion criteria
1. Initial treatment of lung adenocarcinoma confirmed by pathology or cytology
2. Classic mutation of EGFR gene
3. Minimum life expectancy 3 months
4. Patients with clinical stage III ~ IV were considered as advanced lung cancer after comprehensive evaluation of imaging, medical history and examination at the same time, and were excluded from other malignant tumors

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
103

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/01/2017

Date of final enrolment
01/09/2020

Locations

Countries of recruitment
China

Study participating centre
Fujian Provincial Hospital
No.134 East Street
Fuzhou
China
350001

Sponsor information

Organisation
Fujian Provincial Hospital

ROR
https://ror.org/045wzwx52

Funder(s)

Funder type
Research organisation

Funder Name
Tianqing Medical Science Development Fund

Results and Publications

Individual participant data (IPD) sharing plan
Raw data can be obtained by contacting Ting Li (fjslzjp@163.com). The type of data: Patients' information in Excel format. Duration: Forever available. The data will be shared with researchers who also study lung cancer, for dataset analysis, using statistical methods. Consent from participants was obtained. Data were anonymized.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/12/2022	20/04/2023	Yes	No