ISRCTN16840270 https://doi.org/10.1186/ISRCTN16840270

Therapeutic drug monitoring of linezolid in Chinese patients

Submission date 27/08/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 27/08/2024	**Overall study status** Ongoing	
Last Edited 27/08/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Linezolid is an antibiotic with a wide spectrum of antibacterial properties. There is still controversy over the individualized dosing regimen of linezolid. Therefore, it is particularly important to conduct studies in the Chinese patient population to determine the optimal therapeutic drug monitoring concentration range of linezolid and identify the risk factors for adverse reactions. This study established a research cohort for drug monitoring of linezolid treatment through a nationwide multicenter collaboration.

Who can participate?
Patients aged 18 years and over currently receiving treatment with linezolid

What does the study involve?
This study involved collecting blood samples from patients for 2 days, 6 times, and conducting a 28-day follow-up.

What are the possible benefits and risks of participating?
This study can help us find the optimal concentration range of linezolid and prevent adverse reactions. The risk of this study is relatively low, with the majority of risks being the possibility of slight discomfort during blood collection.

Where is the study run from?
Changxing People's Hospital (China)

When is the study starting and how long is it expected to run for?
December 2023 to September 2025

Who is funding the study?
1. Zhejiang Pharmaceutical Association (China)
2. Key Laboratory of Intelligent Pharmacy and Individualized Therapy of Huzhou (China)

Who is the main contact?
Bin Lin, lb_wzmc@126.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KY-IIT-20240701

Study information

Scientific Title
Therapeutic drug monitoring of linezolid in Chinese patients: a prospective, multicenter, observational study

Acronym
TULIP

Study objectives
Clarify the safety of linezolid Css in the Chinese patient population at 2-8 mg/L, as well as the increased risk of blood toxicity beyond 8 mg/L.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 16/08/2024, Changxing People's Hospital Ethics Committee for Clinical Research (2F-6# Building, No. 66 Taihu Road, Changxing, 313100, China; +86 (0)13511248946; cxmedethics@126.com), ref: 2024-EC-070

Study design
Prospective multicenter observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Safety

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients receiving treatment with linezolid

Interventions
This study collected three venous blood samples from patients on the 3rd and 7th day after receiving linezolid treatment, 30 minutes before the start of administration (trough concentration, Cmin), 30 minutes after the end of infusion (peak concentration, Cmax), and 3 hours after the end of infusion. Continuous follow-up for 28 days to observe the occurrence of adverse events.

Intervention Type
Drug

Pharmaceutical study type(s)
Pharmacokinetic

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Linezolid

Primary outcome measure
1. Steady-state concentration (Css) of linezolid measured using UPLC-MS/MS on the 3rd and 7th day after medication
2. Incidence of thrombocytopenia evaluated through blood routine and adverse reaction records

during the treatment period from the first day to the 28th day after medication
3. Incidence of anemia evaluated through blood routine and adverse reaction records during the treatment period from the first day to the 28th day after medication
4. Incidence of leukopenia evaluated through blood routine and adverse reaction records during the treatment period from the first day to the 28th day after medication
5. Incidence of other adverse reactions evaluated through blood routine and adverse reaction records during the treatment period from the first day to the 28th day after medication

Secondary outcome measures
1. Creatinine clearance rate measured using picric acid method on the 3rd and 7th day after medication
2. Duration of linezolid use recorded using case report form (CRF) during the treatment cycle
3. Concomitant use of other antibiotics recorded using case report form (CRF) during the treatment cycle
4. Underlying diseases recorded using case report form (CRF) during the treatment cycle
5. Neutrophil levels measured using automatic classification and counting method for blood cells on the 3rd and 7th day after medication
6. CRP levels measured using immunoturbidimetry on the 3rd and 7th day after medication
7. Procalcitonin levels measured using enzyme immunoassay on the 3rd and 7th day after medication
8. IL-6 levels measured using enzyme immunoassay on the 3rd and 7th day after medication

Overall study start date
12/12/2023

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Age ≥18 years old, male or female
2. Received intravenous anti-infective treatment with linezolid for suspected or confirmed Gram-positive bacterial infection, and should be treated for at least 2 days upon inclusion
3. Patients willing to undergo therapeutic drug monitoring

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Previously received treatment with linezolid (either orally or intravenously) within the past month
2. Pregnant women
3. Child patients
4. Patients who refuse to be enrolled or are unable to obtain blood samples due to reasons such as unwillingness to cooperate with their family members
5. The patient's condition is critical and the estimated survival time is less than 48 hours

Date of first enrolment
01/09/2024

Date of final enrolment
31/08/2025

Locations

Countries of recruitment
China

Study participating centre
Changxing People's Hospital
No. 66 Taihu Road
Changxing
China
313100

Study participating centre
Ren Ji Hospital, Shanghai Jiao Tong University School of Medicine
160 Pujian Road
Shanghai
China
200127

Study participating centre
The Second Affiliated Hospital of Xi'an Jiaotong University
157 West Fifth Road
Xi'an
China
710004

Study participating centre

The First Affiliated Hospital of Wenzhou Medical University
Shangcai Nanbaixiang
Wenzhou
China
325000

Study participating centre
Ruijin Hospital, Shanghai Jiao Tong University School of Medicine
197 Ruijiner Road
Shanghai
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200025

Sponsor information

Organisation
Zhejiang Pharmaceutical Association

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Sponsor type
Research organisation

Website
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Organisation
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Sponsor type
Research organisation

Funder(s)

Funder type
Other

Funder Name
Zhejiang Pharmaceutical Association

Alternative Name(s)
, ZIPA

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
China

Funder Name
Key Laboratory of Intelligent Pharmacy and Individualized Therapy of Huzhou

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal after the end of the study.

Intention to publish date
30/09/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication