

Therapeutic drug monitoring of linezolid in Chinese patients

Submission date 27/08/2024	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/08/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 27/08/2024	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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 C_{ss} 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

Study type(s)

Safety

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, C_{min}), 30 minutes after the end of infusion (peak concentration, C_{max}), and 3 hours after the end of infusion. Continuous follow-up for 28 days to observe the occurrence of adverse events.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Linezolid

Primary outcome(s)

1. Steady-state concentration (C_{ss}) 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

Key secondary outcome(s)

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

Completion date

30/09/2025

Eligibility

Key inclusion criteria

1. Age \geq 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

China

200025

Sponsor information

Organisation

Zhejiang Pharmaceutical Association

Organisation

Key Laboratory of Intelligent Pharmacy and Individualized Therapy of Huzhou

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**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