Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Evaluation of the effect of vitamin B6 compared to placebo on the change of blood cells count in patients with chronic osteomyelitis using linezolid

Protocol summary

Study aim
Evaluation of the effect of vitamin B6 in the prevention of linezolid-induced cytopenia

Design
Randomized, Parallel Group, Placebo-Controlled Clinical Trial

Settings and conduct
This study will be performed in Al-Zahra hospital affiliated to Isfahan University of Medical Sciences. Patients with chronic osteomyelitis who receive linezolid with the dose of 600 mg BID and met the inclusion criteria, will be randomly assigned to two groups of drug and placebo. The patients in drug group will receive oral vitamin B6 with the dose of 40 mg twice daily for 14 days that will be started concurrently with linezolid, while the patients in placebo group will receive placebo tablets with the same dose and duration. Serum level of hemoglobin (Hgb) as well as WBC and platelet count will be recorded before the start of intervention, and at the end of the first, the second, and third weeks of intervention for all patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Manifestation with chronic osteomyelitis 2. Receiving linezolid Exclusion criteria: 1. Serum level of Hgb less than 8 g/dL 2. White blood cell count less than 4500 cells/mm3 3. Blood platelet count less than 50000 cells/mm3

Intervention groups
Drug group: Vitamin B6 tablet (manufactured by Iran Hormone company), 40 mg orally, twice daily, for 14 days Placebo group: Placebo tablet (manufactured by Isfahan Faculty of Pharmacy), one tablet orally, twice daily, for 14 days

Main outcome variables
Serum level of hemoglobin, WBC count, platelet count

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150721023282N13**
Registration date: **2020-08-20, 1399/05/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-20, 1399/05/30**
Update count: **0**

Registration date
2020-08-20, 1399/05/30

Registrant information

Name
Rasool Soltani

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3792 7067

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of vitamin B6 compared to placebo on the change of blood cells count in patients

with chronic osteomyelitis using linezolid

Public title
Evaluation of the effect of vitamin B6 on blood cells count in patients using linezolid
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Manifestation with chronic osteomyelitis Use of linezolid
Exclusion criteria:
Serum level of Hgb less than 8 g/dL WBC count less than 4500 cells/mm3 Platelet count less than 50000 cells/mm3
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method was used in which blocks of 4 were used.
Blinding (investigator's opinion)
Double blinded
Blinding description
Drug (vitamin B6) and placebo tablets will be fully similar and packaged in similar containers. The patient, the prescriber (physician), data analyst, and the laboratory personnel will be blind to the content of containers and intervention type.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Hezar-Jerib Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-07-11, 1399/04/21
Ethics committee reference number
IR.MUI.MED.REC.1399.289

Health conditions studied

1

Description of health condition studied
drug-induced pancytopenia
ICD-10 code
D61.811
ICD-10 code description
Other drug-induced pancytopenia

Primary outcomes

1

Description
White blood cell count
Timepoint
Before the intervention, the end of weeks 1, 2, and 3 of intervention
Method of measurement
Flow cytometry

2

Description
Serum level of hemoglobin
Timepoint
Before the intervention, the end of weeks 1, 2, and 3 of intervention
Method of measurement
Flow cytometry

3

Description
Blood platelet count
Timepoint
Before the intervention, the end of weeks 1, 2, and 3 of intervention
Method of measurement
Flow cytometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Vitamin B6 tablet (manufactured by

Iran Hormone Company), 40 mg, twice daily, for 14 days

Category

Prevention

2

Description

Control group: Placebo tablet (manufactured by Isfahan Faculty of Pharmacy), one tablet, twice daily, for 14 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Kiana Shirani

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Soffeh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Kiana Shirani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Confidentiality of patients data
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available