

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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)

Phone

+98 31 3792 7067

Email address

soltani@pharm.mui.ac.ir

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

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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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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Kiana Shirani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Hezar-Jerib Ave.

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Province**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