Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of vancomycin loading dose effect on clinical outcome in patients with diabetic foot infection: a randomize, double blind clinical trial

Protocol summary

Study aim

Clinical outcomes in patients with diabetic foot infection in two groups receiving vancomycin loading dose and the group not receiving it Comparison of the occurrence of acute kidney injury in patients with diabetic foot infection in two groups receiving vancomycin loading dose and the group not receiving it. Comparison of laboratory results in patients with diabetic foot infection in two groups receiving vancomycin loading dose and the group not receiving it.

Design

مطالعه کارآزمایی بالینی دوسویه کور است که توسط آمار و بلوک جایگشتی تصادفی سازی شده است.

Settings and conduct

Shahid Sadoughi Hospital, Yazd, Diabetic foot patients are evaluated based on randomization and double-blinding under the influence of loading dose compared to not receiving it.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic foot patients older than 18 years who are hospitalized for at least 7 days. Exclusion criteria: Allergy to vancomycin, obese people, breastfeeding and pregnancy, dialysis people, resistant microorganism, and patients who are under antibiotic treatment for other reasons or during They received antibiotics 48 hours ago.

Intervention groups

Eighty patients are selected, 40 of them will receive the vancomycin loading dose before starting the maintenance dose, and 40 will receive only maintenance doses.

Main outcome variables

Clinical outcomes in patients with diabetic foot infection, comparison of the occurrence of acute kidney injury in patients, comparison of laboratory results

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240729062573N1**
Registration date: **2024-09-16, 1403/06/26**
Registration timing: **prospective**

Last update: **2024-09-16, 1403/06/26**
Update count: **0**

Registration date

2024-09-16, 1403/06/26

Registrant information

Name
Nazanin Nematelahi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3833 2762
Email address
nematelahinazanin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of vancomycin loading dose effect on clinical outcome in patients with diabetic foot infection: a randomize, double blind clinical trial

Public title
The effect of vancomycin loading dose in diabetic foot patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diabetic patients over 18 years of age with purulent drainage, swelling, and redness in the leg area below the knee who are admitted to the infectious department of Shahid Sadoughi Hospital in Yazd and are candidates for treatment with vancomycin injection form to treat diabetic foot infection Receive vancomycin for at least 7 days

Exclusion criteria:
history of sensitivity to vancomycin BMI≥30 vancomycin-resistant microorganism in the antibiogram Pregnancy, breastfeeding under hemodialysis, peritonealdialysis, or CCRT Patients who have had effective antibiotic therapy with an effective dose and treatment period during the last 48 hours are excluded from the study unless Have evidence of previous antibiotic treatment failure, or antibiotic resistance to previous cases. Patients who are treated with antibiotics for other reasons Patients who are treated with topical antibiotic on diabetic foot ulcer Receiving vancomycin for surgical prophylaxis

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
80 patients This number of patients were selected by randomization method based on permutation block and will be divided into two groups of 40 people Group A received vancomycin loading dose and then receive maintainace doses and in front of B group They only received maintenance doses In both groups, the doses of potency are determined based on the gfr of the patients from the beginning to the end of the study Every patient is visited daily

Blinding (investigator's opinion)
Double blinded

Blinding description
A double-blind study is such that all the above steps will be hidden from the view of the patient and the attending physician, all patients entered into the study have completed the consent form before being assigned to the two study groups, but from their assignment to the control group or They are unaware of medicine. The first operator determines the sequence and specific plan of the patients according to the order of entering the patients into the study and identifies them with code A or B, then determines the appropriate medicine for each person according to the above explanations and places them in special envelopes. The nurse injects it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Faculty of Medicine, Shahid Sadougi University of Medical Sciences, Yazd

Street address
central organization of Shahid Sadoughi university of medical science, Shahid Bahonar square, Yazd Town

City
Yazd

Province
Yazd

Postal code
۸۹۱۵۸۹۶۵۵۱

Approval date
2024-03-13, 1402/12/23

Ethics committee reference number
IR.SSU.MEDICINE.REC.1402.412

Health conditions studied

1

Description of health condition studied
Investigating the effect of vancomycin loading dose in diabetic foot patients

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Comparison of clinical outcomes in patients with diabetic foot infection in two groups receiving vancomycin loading dose and the group not receiving it

Timepoint
At the beginning of the study and during the study for up to 7 days
Method of measurement
Examination of clinical outcome based on clinical manifestations

2

Description
Comparison of laboratory results in patients with diabetic foot infection in two groups receiving vancomycin loading dose and the group not receiving it.
Timepoint
At the beginning of the study and during the study up to 7 days
Method of measurement
Examining laboratory results based on inflammatory factors, Erythrocyte Sedimentation rate and C-reactive protein and white blood cell count

3

Description
Comparison of the occurrence of acute kidney injury in patients with diabetic foot infection in two groups receiving vancomycin loading dose and the group not receiving it.
Timepoint
At the beginning of the study and during the study up to 7 days
Method of measurement
Assessment of acute kidney injury based on serum creatinine and urine volume

Secondary outcomes

empty

Intervention groups

1

Description
Forty drug candidate patients receiving Laoding dose with a dose (20-35 mg/kg) of 25 mg/kg vancomycin (vancomycin injection vial of Dena Pharmaceutical Company) (maximum 2 grams, even in patients with a weight of more than 80 kg, a loading dose of more than 2 grams was given (can't) infusion within 2 hours and then receiving a maintenance dose (15-20 mg/kg/dose every 8 to 12 hours) in the amount of 500 to 2000 mg (for every 500 mg of vancomycin, infusion should be done for 30 minutes) Based on the GFR calculated from the Cockrauf-Gault formula,
Category
Treatment - Drugs

2

Description
Control group: forty drug candidate patients without receiving the loading dose of vancomycin (without receiving the loading dose) received maintenance doses of vancomycin (Vancomycin injection vial of Dana Pharmaceutical Company) with a dose of 15-20 mg/kg/dose every 8 to 12 hours (calculated based on GFR from the Cockrauf-Gault formula) and the infusion rate should be 30 minutes per 500 mg of vancomycin.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Nazanin Nematelahi
Street address
Faculty of Medicine,Shahid Sadoughi university of Medical Sciences,Alem Square, Shohaday Gomnam Blvd, Yazd Town
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۸۹۶۵۵۱
Phone
+98 35 3833 2762
Email
Nematelahinazanin@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Amin Salehi Abarghoee
Street address
Research and Technology Vice-Chancellor, Imam Reza (AS) Educational Complex, Student Blvd,Imam Hossein (AS) Square, Yazd Town
City
Yazd
Province
Yazd
Postal code
۸۹۱۵۸۹۶۵۵۱
Phone
+98 35 3628 8114
Email
m.gmail@editormshsj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source
100

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
Yazd University of Medical Sciences

Full name of responsible person
Nazanin Nematelahi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Infectious diseases

Street address
Faculty of Medicine,Shahid Sadoughi university of Medical Sciences,Alem Square, Shohaday Gomnam Blvd, Yazd Town

City
Yazd

Province
Yazd

Postal code
۸۹۱۰۸۹۶۵۵۱

Phone
+98 35 3820 3865

Email
Nematelahinazanin@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Nazanin Nematelahi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Infectious diseases

Street address
Faculty of Faculty of Medicine, Shahid Sadoughi university of Medical Sciences,Alem Square, Shohaday Gomnam Blvd, Yazd Town

City
Yazd

Province
Yazd

Postal code
۸۹۱۰۸۹۶۵۵۱

Phone
+98 35 3820 3865

Email
Nematelahinazanin@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
NazaninNematelahi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Infectious diseases

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Province
Yazd

Postal code
۸۹۱۰۸۹۶۵۵۱

Phone
+98 35 3820 3865

Email
Nematelahinazanin@gmail.com

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
There is no further information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available