Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison Efficiency of Six-Weeks Versus Twelve-Weeks Administration of Clindamycin and Ciprofloxacin in Treatment of Diabetic Foot Osteomyelitis Without Surgical Indication

Protocol summary

Summary

(1) Objectives: Comparison efficiency of six-weeks versus twelve-weeks administration of clindamycin and ciprofloxacin in treatment of diabetic foot osteomyelitis without surgical indication based on the size of the wound, some biochemical and hematology parameters, bone probe test, culture of wound secretion, age and gender of patients, common aerobic bacterial causes of osteomyelitis and determine the antibiotic resistance of common bacterial causes of osteomyelitis in the studied population. (2) Design: The study will be intervention (experimental), including 30 patients with diabetic foot osteomyelitis without surgical indication consulted to diabetes clinic of Imam Khomeini hospital and hospitalized cases in the internal sector of there. (3) Setting and conduct: samples will be equally divided into the 6 and 12 weeks of treatment with antibiotics (ciprofloxacin + clindamycin) groups. All of the obtained variables will be classified according to the recovery or non-recovery status of patients. (4) Participants including major eligibility criteria: including criteria: confirmation of osteomyelitis in patients with diabetic foot; the absence of obesity, chronic systemic diseases and drug resistance to ciprofloxacin and clindamycin, and exclusion criteria included: the need surgical intervention at any time of the study, the presence of any of the disorders during the study follow-up and treatment of diseases, resistance of the causes against to the used antibiotics, lack of anterior and posterior leg pulses, and pregnancy. (5) Intervention: The intervention will be done when 6 or 12 weeks. (6) Main outcome measures (variables): they will be lower ESR and leukocytosis, and wound healing.

General information

Acronym

DFO

IRCT registration information

IRCT registration number: **IRCT2016110830793N1**
Registration date: **2017-04-08, 1396/01/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-08, 1396/01/19

Registrant information

Name

Elnaz Afrozeh

Name of organization / entity

Ardabil Medical University

Country

Iran (Islamic Republic of)

Phone

+98 41 3381 2998

Email address

e.afrozeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Dr. Shahram Habib Zadeh, Vice Chancellor for Research, Ardabil University of Medical Sciences. Address: End of University Avenue, Office Complex Medical University, Vice Chancellor for Research, Ardabil University of Medical Sciences, Ardabil, Tel: 00984533522089, Email: research@arums.ac.ir.

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Efficiency of Six-Weeks Versus Twelve-Weeks Administration of Clindamycin and Ciprofloxacin in Treatment of Diabetic Foot Osteomyelitis Without Surgical Indication

Public title

Efficiency of Clindamycin and Ciprofloxacin in Treatment of Diabetic Foot Osteomyelitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion main criteria: confirmed the diagnosis of osteomyelitis with no surgery in patients with diabetic foot; absence of chronic liver, renal, coronary arteries, anemia, rheumatism,...; absence of resistance against ciprofloxacin and clindamycin; no recent use of ciprofloxacin and clindamycin; absence of marked obesity (BMI more than 30) Exclusion main criteria: surgical intervention at any time of the study; any disorder factors during the study follow-up and treatment; absence of etiologic agents resistance against the used antibiotics; absence of posterior and anterior pulse (by arterial Doppler test); pregnancy and absence of drug gastrointestinal complications; existence of drug complication against ciprofloxacin and clindamycin during the study; resistance against ciprofloxacin and clindamycin.

Age

From **30 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil medical university

Street address

End of University Avenue, Office Complex Ardabil Medical University, Ardabil, Postal Code: 85991-56189, Tel: 0984553522247-53.

City

Ardabil

Postal code

Approval date

2016-04-20, 1395/02/01

Ethics committee reference number

IR-ARUMS-REC-1395-54

Health conditions studied

1

Description of health condition studied

Diabetic foot osteomyelitis

ICD-10 code

M86.8

ICD-10 code description

Other osteomyelitis

Primary outcomes

1

Description

radiography

Timepoint

At the begining and end of the study

Method of measurement

Inflammation and air in the soft tissue, cortical bone destruction, irregular margins of skin at the wound site and in chronic cases of cortical erosions-reaction Periosteal, sclerosis and squestra.

2

Description

Hb A1c

Timepoint

At the begining and end of the study

Method of measurement

%, chromatography

3

Description

ESR

Timepoint

At the begining and every two weeks until the end of the study

Method of measurement

mm/hr, ESR reader

4

Description
positive probing test
Timepoint
At the begining of the study
Method of measurement
Touch or contact with prob

5

Description
FBS
Timepoint
at least 8 hrs fasting then at the begining and every two weeks until the end of the study
Method of measurement
mg/dl, autoanalyser

6

Description
2h pp Glu
Timepoint
at 2 hrs after glucose administration at the begining and every two weeks until the end of the study
Method of measurement
mg/dl, autoanalyser

7

Description
creatinine
Timepoint
at the begining and end of the study
Method of measurement
mg/dl, autoanalyser

8

Description
albumin
Timepoint
at the begining and every two weeks until the end of the study
Method of measurement
g/dl, autoanalyser

9

Description
the surface and depth measure of the ulcer
Timepoint
at the begining and end of the study
Method of measurement
mm2

10

Description
microbial culture and antibiogram
Timepoint
at the begining of the study
Method of measurement
S or R, culture in microbial media and biochemical test

11

Description
Blood cell count
Timepoint
at the begining and every two weeks until the end of the study
Method of measurement
*10 9 /L, hematology cell counter

12

Description
WBC diff count
Timepoint
at the begining and every two weeks until the end of the study
Method of measurement
*10 9 /L, hematology cell counter

13

Description
CRP
Timepoint
at the begining and every two weeks until the end of the study
Method of measurement
mg/dl, Nycocard

14

Description
RBC indices: MCV, MCH, MCHC
Timepoint
at the begining and every two weeks until the end of the study
Method of measurement
fl, pg, %, Hematology cell counter

15

Description
BMI
Timepoint
at the begining of the study
Method of measurement
kg/m2, determination based weight/height2

Secondary outcomes

empty

Intervention groups

1

Description
Tab. ciprofloxacin 500 mg, PO, BD, 6 weeks Cap. clindamycin 300 mg, PO, TDS, 6 weeks
Category

Treatment - Drugs

2

Description
Tab. ciprofloxacin 500 mg, PO, BD, 12 weeks Cap. clindamycin 300 mg, PO, TDS, 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic of Ardabil Imam Khomeini Hospital
Full name of responsible person
Mahnaz Ghannadi Asl
Street address
Ardabil Imam Khomeini Hospital, Ataei St., Ardabil.
City
Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Ardabil University of Medical Sciences
Full name of responsible person
Dr.Shahram Habib Zadeh
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End of University Avenue, Office Complex Medical University, Vice Chancellor for Research, Ardabil University of Medical Sciences, Ardabil
City
Ardabil
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Ardabil University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ardabil Medical University
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Elnaz Afrozeh
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty