Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the efficacy of vitamin D in the treatment of diabetic foot ulcers

Protocol summary

Study aim
Determine the effectiveness of vitamin D in the treatment of diabetic foot ulcers

Design
A randomized, triple blind clinical trial, based on patients with diabetic foot ulcers, which has two parallel groups.

Settings and conduct
Diabetes is one of the most common metabolic diseases that one of the most important is diabetic foot ulcer. Current treatments for diabetic foot ulcers included: Wash and wound dressing; debridement; use of Campfield dressings;Use Leech Therapy and finally, cutting off the part of the leg that has been severely infected.In some studies, the effect of vitamin D on the control and treatment of diabetic foot ulcers has been mentioned but these results in various studies, are contradictory and it is necessary that effect of this vitamin on the control of diabetic foot ulcer, to be specified.This study is a randomized controlled clinical trial that doing in Imam Hossain Hospital of Shahroud. In this study patients, the person responsible for grouping patients and the person responsible for wound healing and prescribing the medicine have been blinded.

Participants/Inclusion and exclusion criteria
64 patients with diabetic foot ulcers age limited 15-70 years old who suffering to type 2 diabetes and no history of antibiotic use and osteomyelitis, are included in the study.

Intervention groups
In the intervention group; Vitamine D was used to evaluate its efficacy in diabetic foot ulcers , along with routine diabetic foot ulcers therapy. In the control group; only routine diabetic foot ulcers therapy has been used.

Main outcome variables
Measure the area and depth of the diabetic foot ulcer that before, 4 weeks, 8 weeks and 12 weeks after intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100102002954N12**
Registration date: **2018-09-22, 1397/06/31**
Registration timing: **prospective**

Last update: **2018-09-22, 1397/06/31**
Update count: **0**

Registration date
2018-09-22, 1397/06/31

Registrant information

Name
Mohammad Bagher Sohrabi

Name of organization / entity
Shahroud University of Medical Ssciences and Health

Country
Iran (Islamic Republic of)

Phone
+98 23 3239 5054

Email address
mb.sohrabi@shmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2018-12-22, 1397/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy of vitamin D in the treatment of diabetic foot ulcers

Public title
The effect of vitamin D in the treatment of diabetic foot ulcers

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diabetic foot ulcer Suffering to Type 2 diabetes Satisfaction in rasarach

Exclusion criteria:
Pregnancy The presence of autoimmune disease Use of anticonvulsants Antibiotic use in the last two months low blood pressure Osteomyelitis The need for a large debridement Inadequate kidny Skin tumors on the wound Lack of sense in the lower limbs Dissatisfaction in rasarach

Age
From **15 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software; Sequence Building: Using randomized 4 in 4 blocks; Hiding method: Use envelopes in the package

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study, patients, project executives, and person responsible for wound healing and recording it are blinded.The division of patients into two groups A and B is done by a qualified nurse who has no knowledge of the actions performed in the two groups. Do wound examination, drugs Prescribing and results recorder will be done by a qualified nurse without any knowledge of the type of medicine and patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences

Street address
Research Deputy; Shahroud University of Medical Sciences; Haft Tir Square

City
Shahroud

Province
Semnan

Postal code
3614773947

Approval date
2018-05-23, 1397/03/02

Ethics committee reference number
IR.SHMU.REC.1397.035

Health conditions studied

1

Description of health condition studied
Diabetic foot ulcer

ICD-10 code
L97

ICD-10 code description
Non-pressure chronic ulcer of lower limb, not elsewhere classified

Primary outcomes

1

Description
Diabetic foot ulcer area

Timepoint
Before, 4 weeks, 8 weeks and 12 weeks after intervention

Method of measurement
With Auto cad 2010

2

Description
Depth of diabetic ulcers

Timepoint
Before, 4 weeks, 8 weeks and 12 weeks after intervention

Method of measurement
ulcers will be evaluated according to University of Texas Foot Wound Classification System

Secondary outcomes

1

Description
Serum CRP
Timepoint
Before, 4 weeks, 8 weeks and 12 weeks after intervention
Method of measurement
In a quantitative laboratory method

2

Description
Serum WBC
Timepoint
Before, 4 weeks, 8 weeks and 12 weeks after intervention
Method of measurement
In laboratory method

Intervention groups

1

Description
Intervention group: for patients in the intervention group; administration of 50000 units of vitamin D per week, together with routine diabetic foot ulcer treatment during the study
Category
Treatment - Drugs

2

Description
Control group: for patients in the control group; only administration of routine diabetic foot ulcer treatment during the study
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossain Hospital
Full name of responsible person
Dr. Ehsan Nezakati
Street address
Imam Hossain Hospital, Imam street
City
Shahroud
Province
Semnan
Postal code
3616611151
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
drenezakati@shmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hassan Emamian
Street address
Research deputy; Shahroud University of Medical Sciences; Haft Tir Square
City
Shahroud
Province
Semnan
Postal code
3614773947
Phone
+98 23 3239 4499
Fax
+98 23 3239 4800
Email
pajouhesh@shmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
The personal budget of researchers
Proportion provided by this source
90
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Bagher Sohrabi
Position
Education manager of medical faculty
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Shahroud University of MedicalSciences and Health, Shahroud
City

Shahroud
Province
Semnan
Postal code
3614773947
Phone
+98 23 3239 5054
Fax
+98 23 3239 4800
Email
mb.sohrabi@shmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mahsa Azimi
Position
General Practitioner
Latest degree
Medical doctor
Other areas of specialty/work
Medical Education
Street address
Imam Hossain Hospital; Imam Street
City
Shahroud
Province
Semnan
Postal code
3616611151
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
m.azimi458@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mahsa Azimi
Position
General practitioner
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
Imam Hossain Hospital; Imam Street
City
Shahroud
Province
Semnan
Postal code
3616611151
Phone
+98 23 3234 2000
Fax
+98 23 3233 3902
Email
m.azimi458@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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