

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 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)

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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 kidney 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

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Person responsible for scientific inquiries

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Mahsa Azimi

Position

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Latest degree

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Other areas of specialty/work

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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