Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of boron based gel on the treatment of diabetic foot ulcers and infections

Protocol summary

Study aim

The effect of boron based gel on the treatment of diabetic foot ulcers and infections

Design

0.2% Chlorhexidine Dggluconate + 3% Pentahydrate Phenytoinate Gel will be used at least 20 and maximum 30 days. Control group: Treatment of topical ulcers in a method other than the procedure. With 95% confidence, the test power was 95% and using G-Power software, the minimum sample size required was 167. With an estimated 20 percent drop in sample size, the number increased to 400 total. The type of study is a type of interventional study and clinical trial.

Settings and conduct

A clinical, controlled, randomized, and blind clinical trial will be conducted. Classification of the wound and infection of the diabetic foot of the patient are based on the University of Texas system.. In the group treated with 0.2% chlorhexidine digluconate + 3% sodium pentahydrate Pentahydrate twice daily with or without systemic antibiotics is used depending on the patient's condition. In the control group, local ulcers are treated in a way other than the method. Total duration of use is 0.2% chlorhexidine digluconate + 3% sodium pentahydrate Pentahydrate at least 20 days but less than 30 days.

Participants/Inclusion and exclusion criteria

Patients who agree to enroll in the study Patients with diabetic foot ulcer/ or infection Patients older than 18 years of age and below 75 years Patients with or without type 1 diabetes mellitus or infection

Intervention groups

0.2% Chlorhexidine digluconate + 3% sodium glycol Phenytoinate Phenytoinate at least 20 and maximum 30 days with systemic antibiotics. Treatment of topical ulcers in a way other than mentioned

Main outcome variables

The aim of this clinical trial is to evaluate the effectiveness of 0.2% chlorhexidine digluconate + 3% sodium pentahydrate pentahydrate sodium on wound healing and diabetic foot infections.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190212042686N1**
Registration date: **2019-04-16, 1398/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-16, 1398/01/27**
Update count: **0**

Registration date

2019-04-16, 1398/01/27

Registrant information

Name

majid Mobasseri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8939

Email address

mobasserim@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of boron based gel on the treatment of diabetic foot ulcers and infections

Public title
The effect of boron based gel on the treatment of diabetic foot ulcers and infections
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with diabetic foot ulcer/ or infection Patients who agree to enroll in the study. Patients older than 18 years of age and below 75 years Patients with or without type 1 diabetes mellitus or infection Patients who can be treated at outpatient clinics. Patients who are admitted to treatment.
Exclusion criteria:
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **400**
Randomization (investigator's opinion)
Randomized
Randomization description
Given the fact that the sample size is the same in both groups, we use the Excel software and the formula = Rand () to randomize and to increase the precision and balance of the samples in the randomization (for any reason Patient will withdraw from the plan) We use several blocks per group. It will also be provided to the physician to cover the allocation of matte envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
A gel that has an active ingredient in boron with a gel that does not have a substance and is used as a placebo is completely identical in terms of the shape and size of the container, and the gels themselves do not differ in terms of odor and color, and are completely indistinguishable. (This action was taken by the pharmaceutical company). The important point is that the patient is told that the gel used for the patient may be medication or medication. Clinicians and blind patients will be blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz - Azadi St. - Golghast St. - Central Office of Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2018-12-03, 1397/09/12
Ethics committee reference number
IR.TBZMED.REC.1397.727

Health conditions studied

1

Description of health condition studied
diabetic foot ulcer and infections
ICD-10 code
E12
ICD-10 code description
Malnutrition-related diabetes mellitus

Primary outcomes

1

Description
Wound area
Timepoint
25 to 30 days
Method of measurement
Clinical evaluation

2

Description
The size of the wound
Timepoint
25 to 30 days
Method of measurement
Clinical evaluation

3

Description
Depth of wound
Timepoint

25 to 30 days
Method of measurement
Clinical evaluation

4

Description
Infection in the wound
Timepoint
25 to 30 days
Method of measurement
Clinical evaluation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 0.2% Chlorhexidine Dggluconate + 3% Pentahydrate Phenytoinate Sodium Gel will be used at least 20 and maximum 30 days with or without systemic antibiotics.
Category
Treatment - Drugs

2

Description
Control group: Treatment for topical ulcers in a way other than mentioned
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital and clinic of Salamat
Full name of responsible person
Majid Mobasseri
Street address
Golestan
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5166614766
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+98 41 3337 3901
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mobasserimajid@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
A. Ghasem Jouyban
Street address
Golgasht Street
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Tabriz
Province
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+98 41 3335 9680
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Majid Mobasseri
Position
Professor
Latest degree
Medical doctor
Other areas of specialty/work
Endocrinology
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Endocrine & Metabolism Department, Fourth Floor, Imam Reza Hospital, Golghast St, Tabriz, East Azarbaijan
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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

A portion of the data will be shared.

When the data will become available and for how long

2019

To whom data/document is available

University researchers and professors

Under which criteria data/document could be used

For further studies

From where data/document is obtainable

by Email

What processes are involved for a request to access data/document

21/5000 Request via email

Comments