Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Phone

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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

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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

Street address

Endocrine & Metabolism Department, Fourth Floor, Imam Reza Hospital, Golghast St, Tabriz, East Azarbaijan

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
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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

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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