

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of Hypertonic Saline Solution 5% with Normal Saline for Wound Healing in Diabetic Foot Ulcer Patients

Protocol summary

Study aim

Comparison of the effect of 5% hypertonic solution with conventional rinsing method with normal saline in improving diabetic foot

Design

A clinical trial with parallel control group, randomized, phase 3 on 100 patients

Settings and conduct

100 patients with diabetic foot ulcers who referred to Motahari Surgery Clinic in Shiraz in 2015 were entered in the study. The inclusion criteria consisted of patients diagnosed with diabetes type 1 and 2 and ages between 20 to 70 years. DFU patients with osteomyelitis and absence of dorsalis or posterior tibialis pulse, heart failure, fasting blood sugar more than 200, and HbA1C above 7.5 were excluded from the study. The patients were recruited at the Motahari center in which were randomly grouped in the intervention and control group and treatments were modified accordingly. only the Data analyzer was blinded during this study.

Participants/Inclusion and exclusion criteria

Patients with diabetic foot ulcers who referred to Motahari Surgery Clinic in Shiraz in the 2015 were entered in the study. The inclusion criteria consisted of patients diagnosed with diabetes type 1 and 2 and ages between 20 to 70 years. DFU patients with clear gangrene, osteomyelitis, and absence of dorsalis or posterior tibialis pulse, heart failure, fasting blood sugar more than 200, and HbA1C above 7.5 were excluded from the study.

Intervention groups

Rinse diabetic foot ulcer with 5% hypertonic solution as interventional group and comparison with With the conventional method of washing with normal saline as the control group

Main outcome variables

Diabetic foot ulcer healing in terms of size and depth;
Microorganism culture

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200705048015N1**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **retrospective**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

Reza Shahriarirad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3627 5344

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

2015-03-21, 1394/01/01

Actual recruitment end date

2016-03-20, 1395/01/01

Trial completion date

2016-03-20, 1395/01/01

Scientific title

Comparison of Hypertonic Saline Solution 5% with Normal Saline for Wound Healing in Diabetic Foot Ulcer Patients

2016-07-13, 1395/04/23

Ethics committee reference number
IR.SUMS.MED.REC.1395.12

Public title

Hypertonic Saline In Diabetic foot Ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with diabetes type 1 and 2 Age between 20 to 70 years old Diabetic foot ulcer

Exclusion criteria:

Osteomyelitis Absence of dorsalis or posterior tibialis pulse Heart failure Fasting blood sugar more than 200 HbA1C above 7.5

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with a probability of the throw of coin will enter to the intervention and control groups.

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 Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

7134853185

Approval date

Health conditions studied

1

Description of health condition studied

Diabetic foot Ulcer

ICD-10 code

E11.5

ICD-10 code description

Diabetes mellitus With peripheral circulatory complications

Primary outcomes

1

Description

Healing diabetic foot ulcers

Timepoint

6 weeks

Method of measurement

Size and depth of the ulcer

Secondary outcomes

1

Description

Diabetic foot ulcer infection

Timepoint

6 weeks

Method of measurement

Obtaining culture from diabetic foot ulcer

Intervention groups

1

Description

Intervention group: Patients' foot ulcer was cleansed and treated with a 5% hypertonic saline solution in the first group for 6 weeks and 3 times a day. The solution of hypertonic saline was prepared by dissolving 50 grams of salt per liter of cooled water and used 3 times a day. The patients were again examined for size and depth of the ulcer after 6 weeks and the results were recorded. Patients were visited weekly for up to 6 weeks. The amount of solution used was measured and administered to the patient using a measuring container. At the end of the study, the patients were sampled for microbial culture. In the course of admission, each patient who needs a debridement were excluded from the study. The size of the patient's ulcer was again calculated as the longitudinal and transverse diameter of the ulcer with a photograph taken at a distance of 30 centimeters.

Category

Treatment - Other

2

Description

Control group: This group was treated with normal saline 0.9%. The patients were again examined for size and depth of the ulcer after 6 weeks and the results were recorded. Patients were visited weekly for up to 6 weeks. The amount of solution used was measured and administered to the patient using a measuring container. At the end of the study, the patients were sampled for microbial culture. In the course of admission, each patient who needs a debridement were excluded from the study. The size of the patient's ulcer was again calculated as the longitudinal and transverse diameter of the ulcer with a photograph taken at a distance of 30 centimeters.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Bizhan Ziaian

Street address

Namazi square, Motahari Clinic

City

Shiraz

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7193711351

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r.shahriari1995@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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vcrdep@sums.ac.ir

Web page address

<https://research.sums.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Bizhan Ziaian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Namazi Hospital, Zand street

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ziaianb@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Bizhan Ziaian

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Reza Shahriarirad

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

None to declare

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data will be published after deidentification

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

People who are engaged in the this topic are able to ask for the information

Under which criteria data/document could be used

Data of the participant can be requested from the authors. Please write to the correspondence if you are interested in such data.

From where data/document is obtainable

Please write to the correspondence if you are interested in such data.

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

Data will be sent on reasonable request within a few days via email

Comments