Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of topical potassium permanganate 5% solution on foot ulcers in diabetic patients – a randomisad controled clinical trial

Protocol summary

Study aim

Despite the advantages of potassium permanganate, which include its low price, availability and ease of use for patients and its non-toxicity, due to the lack of scientific and research evidence, it still has no place in the treatment of diabetic foot ulcers. Therefore, the aim of this study is to investigate the effect of potassium permanganate in diabetic foot ulcers and its effect on local infection, wound size, wound healing and wound infection control

Design

A randomized clinical trial with a control group, with parallel groups, on 22 patients. The method of randomization will be used in a parallel way from the restricted randomization approach in the method of random allocation rule

Settings and conduct

This study will be conducted in the general surgery clinic and reconstructive surgery clinic of the hospital. Patients are divided into intervention and control groups, and the results of the intervention will be measured on days 0, 7, 14, and 21.

Participants/Inclusion and exclusion criteria

The inclusion criteria is outpatient referral, a diabetic foot ulcer with a Wagner score of 1 or 2, and the presence of a chronic neuropathic diabetic foot ulcer that has been present for at least 3 months. ischemia and progressive infection are exclusion criteria

Intervention groups

Patients are divided into two groups. The first group are candidates for standard diabetic foot ulcer treatment. which includes pressure removal from the diabetic foot ulcer, daily washing and daily examination of the ulcer. The second group are candidates to receive standard treatment plus local solution of potassium permanganate.

Main outcome variables

examination of local infection; degree and size of the wound; Examining the edges of the wound and granulation formation; Duration of complete wound healing and wound infection control on days 0, 7, 14 and 21

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221015056180N1**
Registration date: **2022-11-02, 1401/08/11**
Registration timing: **prospective**

Last update: **2022-11-02, 1401/08/11**
Update count: **0**

Registration date

2022-11-02, 1401/08/11

Registrant information

Name

Afrooz Haghdoost

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 8540

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-06, 1401/08/15

Expected recruitment end date

2023-02-04, 1401/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical potassium permanganate 5% solution on foot ulcers in diabetic patients – a randomisad controled clinical trial

Public title

effect of potassium permanganate solution on diabetic foot

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Outpatient referral Patients with type 2 diabetes Diabetic foot ulcer with Wagner score 1 or 2 Presence of chronic neuropathic and non-ischemic diabetic foot ulcer that has been present for at least 3 months Patients in the age range of 18 to 65 years

Exclusion criteria:

The presence of ischemia symptoms in the lower limbs and ankle-brachial index and toe-brachial index (ABI, TBI) less than 0.7 Advanced wound infection

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Type of randomization: in this research, in order to allocate patients to intervention and control groups, a resticted randomization approach will be used in a parallel way and random allocation rule. To generate random numbers, online randomization will be used at the following address http://www.graphpad.com/quickcalcs/index.cfm Allocation concealment method: Random allocation concealment method will be used for concealment. At the time of registration of eligible patients for the study, using identical sealed envelopes with random sequence, the patient will be a candidate to receive one of two types of treatment.

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 Guilan University of Medical Sciences

Street address

Deputy of research and technology of Guilan university of medical sciences, Siyadati St, Namju St

City

Rasht

Province

Guilan

Postal code

4144666949

Approval date

2022-08-17, 1401/05/26

Ethics committee reference number

IR.GUMS.REC.1401.292

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

ICDE-10

ICD-10 code description

مربوط به عوارض نورولوژيك و ساير عوارض ديابت

Primary outcomes

1

Description

Local infection of diabetic foot ulcer

Timepoint

Investigation of wound infection at the beginning of the study and then on days 7, 14 and 21

Method of measurement

Based on the examination and determining the Wagner score of diabetic foot ulcer

2

Description

Size of diabetic foot ulcer

Timepoint

Measurement of diabetic foot ulcer at the beginning of the study and then on days 7, 14 and 21

Method of measurement

With examination and caliper device

3

Description
Granulation tissue formation
Timepoint
Examination of granulation tissue formation at the beginning of the study and then on days 7, 14 and 21
Method of measurement
Based on examination of diabetic foot ulcer

Secondary outcomes

1

Description
The duration of complete healing of diabetic foot ulcer
Timepoint
At the beginning of the study and then on days 7, 14 and 21
Method of measurement
Based on the examination of the attending physician

Intervention groups

1

Description
Intervention group: Patients in the intervention group will wash the wound with soap and water every day and then use potassium permanganate 5% solution topically. This solution is bought by the researcher from the pharmacy. And every week, the patient will be given the necessary amount to consume for a week. To prepare a solution of potassium permanganate 5%, the pharmacist combines 5 grams of it with 100 cc of distilled water. (This will be done under standard conditions and by the pharmacist). Patients are instructed to apply the solution with cotton soaked in potassium permanganate to all parts of their diabetic foot ulcer, so that the whole ulcer is covered with the solution and the healthy parts of the skin are not covered with the solution and not to wash the wound with water after that.
Category
Treatment - Drugs

2

Description
Control group: The control group is a candidate to receive the standard treatment of diabetic foot ulcer. The standard treatment of diabetic foot ulcer is as follows: removal and transfer of pressure from the area of diabetic foot ulcer, daily washing of the ulcer with mild soap and water, checking the condition of the ulcer daily.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Velayat hospital
Full name of responsible person
Dr Mohamad reza Mobayen
Street address
Khanali zade St, Namju St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr Mohamad Reza Naghipoor
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Deputy of research and technology, Siadati St, Namju St
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Postal code
4144666949
Phone
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Email
research@gums.ac.ir
Web page address
https://research.gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Dr Afrooz Haghdoost

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

Street address
Burn and Regenerative Medicine Research center, Khanali Zade St, Namjoo St, Velayat hospital,

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Position
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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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
After deidentifying people, all the data obtained from the research, including the demographic information of the samples, clinical information and the results of the intervention can be shared.

When the data will become available and for how long
It is possible to access the results after six months from the publication of the results

To whom data/document is available
Researchers in academic centers and scientific research centers

Under which criteria data/document could be used
In order to data comparison in similar studies, the researchers of academic centers and scientific research centers have the possibility to receive data and re-analyze it if they comply with the principles of ethics in research.

From where data/document is obtainable
Burn and Regenerative Medicine Research Center, Guilan University of Medical Sciences, Rasht, Iran Address: Burn Research Center and Regenerative Medicine, Velayat Hospital (3rd floor), Namjo St., Rasht. Contact phone: +98-1333368540 Dr. Mohammad Reza Mobayen Email

address: Mmobayen@gums.ac.ir

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

Researchers should send a written request to receive data to the relevant email address. The review of the documents and the application is done within two to four weeks. Then, if the necessary conditions are met, the data will be provided to the researchers by the research center.

Comments