Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative analysis of the efficacy of phenytoin and Betadine on healing of diabetic foot ulcer

Protocol summary

Study aim
comparative analysis of the efficacy of phenytoin-betadine and conventional wound dressing in healing of diabetic foot ulcer

Design
A clinical trial with a community-based, practice-oriented control group, with parallel groups, not blinding. Randomized random block method

Settings and conduct
The research sample size consists of 80 patients with diabetic foot(intervention group 105, control group 35) in Imam Reza hospital in Kermanshah city in 2020-2021

Participants/Inclusion and exclusion criteria
Inclusion criteria: hysician and patient satisfaction، Patient alertness (GCS = 15)،Age over 18، do not allergic to to iodine and phenytoin، No pregnancy، Lack of hepatic impairment and renal failure (creatinine level below 2), cancer and osteomyelitis، Do not use immunosuppressive and corticosteroid during the last month، No smoking، Controlled blood sugar، Grade I and II foot ulcers according to Meggit-Wagner Exclusion criteria: Unwillingness to co-operate with a patient or physician Grade III, IV, V foot ulcers according to Meggit-Wagner، Amputation Death،

Intervention groups
Control group:only routine treatments will be performed. Includes daily washing, debridement, gas dressing and antibiotic therapy (based on prescribing physician). Intervention group:Wound, washed daily, up to 8 weeks, with iodine 10% then a phenytoin compound capsule will poure into the wound so that it is covered 1mm.The wound examination is performed by Beta Johnson, Padis and Wagner systems, One, two, three, four, six, eight, ten, and twelve weeks after starting treatment and at the end of the study

Main outcome variables
Length and width, depth, infection, grade of diabetic foot ulcer

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181105041563N5**
Registration date: **2020-07-22, 1399/05/01**
Registration timing: **prospective**

Last update: **2020-07-22, 1399/05/01**
Update count: **0**

Registration date
2020-07-22, 1399/05/01

Registrant information

Name
Somayeh Mahdavikian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3827 9394

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

A comparative analysis of the efficacy of phenytoin and Betadine on healing of diabetic foot ulcer

Public title

A comparative analysis of the efficacy of phenytoin and Betadine on healing of diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Physician and patient satisfaction Patient alertness (GCS = 15) Age over 18 do not allergic to to iodine and phenytoin No pregnancy Lack of hepatic impairment and renal failure (creatinine level below 2), cancer and osteomyelitis Do not use immunosuppressive and corticosteroid during the last month No smoking Controlled blood sugar Grade I and II foot ulcers according to Meggit-Wagner

Exclusion criteria:

Unwillingness to co-operate with a patient or physician Grade III, IV, V foot ulcers according to Meggit-Wagner Amputation Death

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Qualified samples were entered into the study by accessible method and randomly divided intervention group (phenytoin-betadine) and control group(conventional wound dressing) . Blocks were done as follows: To intervention group was assigned A code , and the control group received B code. The study blocks were AB, and BA . the AB block was selected as the first block. Patients were assigned to intervention group (phenytoin-betadine) and control group (conventional wound dressing) , respectively, and this method continued until the samples were completed.

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 Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid Beheshty Blv, Kermanshah University of Medical Sciences, Kermanshah, Iran

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-07-08, 1399/04/18

Ethics committee reference number

IR.KUMS.REC.1399.354

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

L97

ICD-10 code description

Ulcer of lower limb, not elsewhere classified

Primary outcomes

1

Description

Length and width of diabetic foot ulcer

Timepoint

One, two, three, four, six, eight, ten, and twelve weeks after starting treatment and at the end of the study

Method of measurement

ruler

2

Description

grade of diabetic foot ulcer

Timepoint

One, two, three, four, six, eight, ten, and twelve weeks after starting treatment and at the end of the study

Method of measurement

Wagner ,Pedis and Beta johnson scale

3

Description

infection of diabetic foot ulcer

Timepoint

One, two, three, four, six, eight, ten, and twelve weeks after starting treatment and at the end of the study

Method of measurement

Pedis scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Wound, washed daily, up to 8 weeks, with iodine 10% produced by Kimia Daroo then a phenytoin compound capsule produced by Caspian Tamin Pharmaceutical Company will poure into the wound so that it is covered 1mm.The wound examination is performed by Beta Johnson, Padis and Wagner systems, One, two, three, four, six, eight, ten, and twelve weeks after starting treatment and at the end of the study
Category
Treatment - Other

2

Description
Control group:only routine treatments will be performed. Includes daily washing, debridement, gas dressing and antibiotic therapy (based on prescribing physician).The wound examination is performed by Beta Johnson, Padis and Wagner systems, One, two, three, four, six, eight, ten, and twelve weeks after starting treatment and at the end of the study
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Somayeh Mahdavikian
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Vice chancellor for research, Kermanshah University of Medical Sciences, Shahid Beheshty Blv., Kermanshah, Iran
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Web page address
http://www.vc-research.kums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Somayeh Mahdavikian
Position
Faculty Member
Latest degree
Master
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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
Undecided - It is not yet known if there will be 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 on the main outcome of the study is available for sharing.
When the data will become available and for how long
Six months after the publication of the results in the form of the article
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Only to conduct similar studies in other populations.
From where data/document is obtainable
somayeh mahdavikian with below email address: smahdavikia@gmail.com and phone number +98 83 3827 9394
What processes are involved for a request to access data/document
A week after receiving an email or phone call, it will take action.
Comments