

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 Mahdavian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3827 9394

Email address

somayeh.mahdavian@kums.ac.ir

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 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 Mahdavian

Street address

Imam Reza hospital, Baghe abrisham

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Kermanshah

Province

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6715986479

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Email

Somayeh.Mahdavian@kums.ac.ir

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 Beheshti Blv., Kermanshah, Iran

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Email

farid_n32@yahoo.com

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 Mahdavian

Position

Faculty Member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

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Kermanshah University of Medical Sciences
Full name of responsible person
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Position
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Master
Other areas of specialty/work
Nursery
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Person responsible for updating data

Contact

Name of organization / entity
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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

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 mahdavian with below email address:
smahdavia@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