Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of The efficacy of topical Melatonin on healing of diabetic foot ulcers in a double blind placebo-controlled clinical trial

Protocol summary

Study aim
topical efficacy of melatonin on diabetic foot ulcer healing
Design
Clinical trial, with parallel groups, double-blind, randomized, on 36 patients. Randomization outcome will be done in a block of 4 and through using excel software.
Settings and conduct
This study is going to be carried out at the Endocrinology clinics of Imam Khomeini affiliated with the Urmia University of Medical Sciences. Patients will be divided into two groups of 18 subjects. Each patient will receive topical gel of melatonin or placebo for 8 weeks. During the study, patients will receive standard care and treatment regimens for diabetic foot in both groups. The area and number of wounds are measured before the start of treatment and after 4 weeks and then at the end of 2 months. Researcher and patients will be blinded.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years, Grade 1 or 2 diabetic foot ulcers based on wagner, Patients with HgbA1c <=10% , Obtain informed consent Patients Wound size more than one cm2 , Patients with ankle brachial index> 0.4 or Color Doppler Ultrasound with no result of severe lower artery involvement. Exclusion criteria: Need for injectable antibiotics, Allergy to topical melatonin product, Patients with uncontrolled epilepsy , Pregnancy and lactation Underlying skin disease leads to scarring Causes of wounds other than diabetes include trauma, Wounds happened in less than 2 weeks, Patients treated with chemotherapy or radiotherapy,Use of drugs that interfere with wound healing, such as: corticosteroids at least the equivalent dose of 40 mg of prednisolone, mycophenolate, cyclosporine, tacrolimus, rituximab, Patients with renal disease at stage 5 (GFR<15 ml/min)or on dialysis
Intervention groups
Interventional group: receives topical gel of melatonin at night. Control group: receives topical gel of placebo at night
Main outcome variables
wound healing

General information

Reason for update
According to the sample size based on the number of wounds and determination of 50 wounds at the time of registration of the proposal in UMSU, each patient has one wound, 25 people in each group were determined, but currently the number of studied wounds is 50, but the number of patients currently is 26. (Some patients have the same wound in different parts of their legs) need permission to reduce the sample size to 36 people with assuming a drop out 20%.
Acronym
IRCT registration information
IRCT registration number: **IRCT20200220046560N1**
Registration date: **2021-04-09, 1400/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-10, 1402/01/21**
Update count: **1**
Registration date
2021-04-09, 1400/01/20

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-01, 1400/01/12
Expected recruitment end date
2022-03-31, 1401/01/11
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of The efficacy of topical Melatonin on healing of diabetic foot ulcers in a double blind placebo-controlled clinical trial

Public title
Evaluation of The efficacy of topical Melatonin on healing of diabetic foot
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients equal and more18 years old Grade 1 or 2 diabetic foot ulcers based on wagner Patients with HgbA1c<=10% Obtain informed consent The size of the wound is more than one cm2 Index affected by ankle> 0.4 or Color Doppler Ultrasound with no result of severe vascular involvement
Exclusion criteria:
Need to have injectable antibiotics Allergy to topical melatonin product Patients with uncontrolled epilepsy Pregnancy and lactation Any skin disorder leads to ulcer Causes of wounds other than diabetes such as trauma Wounds happened in less than 2 weeks Patients treated with chemotherapy or radiotherapy Use of drugs that interfere with wound healing, such as: corticosteroids at least the equivalent dose of 40 mg of prednisolone, mycophenolate, cyclosporine, tacrolimus, rituximab Patients with renal disease at stage 5(GFR<15 ml/min) or on dialysis
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **36**
More than 1 sample in each individual
Number of samples in each individual: **3**
Some patients have the same wound in different parts of their legs
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization will be used in this study. The size of all blocks is equal and 5 blocks of 10 including 18 patients in the intervention group and 18 patients in the control group will be used.(with considering 20% drop out) To determine the random sequence of drug and placebo allocation within each block, the site https://studyrandomizer.com/ is used and the sequences (sequence within block) are received in the form of an Excel file from the site. The output file will be assigned to each person a four-part code consisting of a letter and three digits separated by commas. In order to conceal random allocation, the method of opaque sealed envelopes with random sequence will be used. thirty six envelopes with aluminum wrappers (in order to obscure the contents of the envelopes) will be prepared and each of the random sequences created on one card will be recorded and the cards will be placed in the envelopes respectively. In order to maintain a random sequence, the envelopes will be numbered in the same way on the outer surface.
Blinding (investigator's opinion)
Double blinded
Blinding description
Both patients and researcher do not know about type of drug that receive (melatonin or placebo) and are blinded. Placebo are prepared in same shape and color of melatonin topical Gel. Drug and placebo are coded in A and B groups with block randomization method. Then they are given to the researcher and patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethics committee of Urmia University of Medical Sciences
Street address
Imam Khomeini Hospital, Ershad Ave., Urmia, I.R.IRAN
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Urmia
Province
West Azarbaijan
Postal code
571478334
Approval date
2021-01-20, 1399/11/01
Ethics committee reference number
IR.UMSU.REC.1399.365

Health conditions studied

1

Description of health condition studied
diabetic foot
ICD-10 code
E11.62
ICD-10 code description
Type 2 diabetes mellitus with skin complications

Primary outcomes

1

Description
wound area
Timepoint
At the baseline (before intervention) and at the fourth week , Eighth week of intervention
Method of measurement
Using photos and area measurements

Secondary outcomes

1

Description
sleep quality
Timepoint
Start of study, eighth week
Method of measurement
sleep questionnaire(Pittsburgh Sleep Quality Index)

2

Description
Life quality
Timepoint
Start of study, eighth week
Method of measurement
Diabetic Foot Ulcer Scale(DFS)

Intervention groups

1

Description
Intervention group: Receive a topical form of melatonin (Razak Pharmaceutical Company) with standard regime(Blood sugar control, regular wound washing, pressure reduction on the wound, treatment with oral antibiotics if needed) and the instruction to use overnight rub into the wound for 8 weeks and the ultimate goal is to use one milligram of melatonin (0.2%) per square centimeter of wound.
Category
Treatment - Drugs

2

Description
Control group: Receive a topical form of placebo (Distilled water, carbomer, TEA) (school of pharmacy)with standard regime and the instruction to use overnight rub into the wound for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes and diabetic foot ulcer treatment clinic affiliated to Urmia University of Medical Sciences
Full name of responsible person
Ayda Esmaeili
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Ayda Esmaeili

Position
Assistant Professor of Clinical Pharmacy

Latest degree
Specialist

Other areas of specialty/work
Medical Pharmacy

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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
Undecided - It is not yet known if there will be 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
average of age, sex, comorbidity, laboratory date

When the data will become available and for how long
article publish time

To whom data/document is available
scientific

Under which criteria data/document could be used

19 / 5000 Translation results Assess the accuracy of the study

From where data/document is obtainable

Responsible for the project

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

Must be notified to the project manager through the journal in which the article was submitted

Comments