

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Oct 2026

The effect of topical insulin and liothyronine on the healing of foot ulcer in patients with type 2 diabetes

Protocol summary

Study aim

Comparison of the effect of topical liothyronine and insulin formulations in improving diabetic foot ulcers in patients with type 2 diabetes

Design

Patients in 3 groups will receive liothyronine Topical cream 0.75%, or combination liothyronine 0.75% and 0.5 IU Ins Reg /100 g cold cream, placebo (Alpha cream) according to standard diabetic foot care by the balanced block randomization method will be divided (each group 26) and twice a day apply a topical cream for 12 weeks.

Settings and conduct

The study will be conducted at the Yazd Diabetes Center in three phases: screening phase (7 days before prescribing the drug in terms of entry criteria), treatment (day zero to 4 weeks), and follow-up phase (2 and 3 months)

Participants/Inclusion and exclusion criteria

Inclusion criteria Exclusion criteria : 1) Patients over 18 years of age with a history of type 2 diabetes and hemoglobin A1C less than 10% 2) Adequate literacy to fill the consent form, study comprehension 3) Diabetic foot ulcer Conditions for leaving the study: 1) Gangrene of the foot 2) Osteomyelitis 3) Severe sepsis 4) History of alcohol consumption or substance abuse 5) History of chronic diseases such as cancers or congestive heart failure, ESRD, liver failure 6) Concomitant use of drugs that can adversely affect the wound healing process: glucocorticoids, immunosuppressive drugs, cytotoxic drugs 7) Failure to sign a written consent 8) Pregnant and lactating women 9) Patients with a history of steroid, cytotoxic or immunosuppressive drugs 10) Patients taking oral atorvastatin

Intervention groups

One group will receive liothyronine topical cream, the other group insulin regular and liothyronine combination topical cream, and the control group will receive topical alpha ointment.

Main outcome variables

Percentage of wound closure per week, time of re-epithelialization 50% and 100%

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N20**

Registration date: **2021-08-22, 1400/05/31**

Registration timing: **prospective**

Last update: **2021-08-22, 1400/05/31**

Update count: **0**

Registration date

2021-08-22, 1400/05/31

Registrant information

Name

Fatemeh Saghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of topical insulin and liothyronine on the healing of foot ulcer in patients with type 2 diabetes

Public title
The effect of topical insulin and liothyronine on the healing of foot ulcer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients over the age of 18 with a history of type 2 diabetes and hemoglobin A1C less than 10% Adequate literacy to fill the consent form, comprehension study Diabetic foot ulcer
Exclusion criteria:
 Gangrene of the foot Osteomyelitis Severe sepsis History of alcohol consumption or substance abuse History of chronic diseases such as cancers or congestive heart failure, ESRD, liver failure Concomitant use of drugs that can adversely affect the wound healing process: glucocorticoids, immunosuppressive drugs, cytotoxic drugs Failure to sign a written consent Pregnant and lactating women Patients taking atrovastatin Patients with a history of steroid, cytotoxic or immunosuppressive drugs

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 78 patients are randomly allocated into three treatment groups (A, B, and C). Block randomization method will be used for random allocation. Twelve blocks of six are considered. The generated permutations include the letters A, B, and C, which are repeated twice (for example, ABCABC) in each permutation. These permutations are generated using Random allocation software version 1. For this purpose, the generated list by the software is from 1 to 78, which are arranged in 12 blocks of six in order. To run this software output, we give the first qualified person number 1 and the last person will receive number 78. To consider blinding in random allocation, the list is given to another person outside the study and using short message service (SMS) before assigning the type of treatment according to the number of eligible people is

asked and thus people enter the study. In addition, in the software output, both numbers 1 to 78 and the permutations of the letters A, B, and C can be seen.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the products have been prepared, the first Executor, the treating physician, and the researcher monitoring the condition of the wounds will not be aware of any of the groupings performed. In this way, after preparing the products, liothyronine cream (150 mg liothyronine powder in 100 gr cold cream) or liothyronine/insulin cream (0.5 ml regular insulin in 99 gr liothyronine cream), these prepared creams and alpha cream (routine care), which all look the same, are placed in similar boxes. Then we ask another person to identify them with the codes A or B or C.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Medicine - Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Gomnam shohada boulevard,shahid sadoughi university of medical sciences

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Province

Yazd

Postal code

8915173143

Approval date

2019-11-03, 1398/08/12

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.236

Health conditions studied

1

Description of health condition studied

Diabetic foot ulcer

ICD-10 code

E11.621

ICD-10 code description

Type 2 diabetes mellitus with foot ulcer

Primary outcomes

1

Description

Percentage of wound closures 1 to 4 per week

Timepoint

Screening phase (7 days prior to drug administration in terms of entry criteria), treatment (day zero to 4 weeks), and follow-up phase (2 and 3 months).

Method of measurement

REEDA score (3-0)

2

Description

Re-epithelialization

Timepoint

Screening phase (7 days prior to drug administration in terms of entry criteria), treatment (day zero to 4 weeks), and follow-up phase (2 and 3 months).

Method of measurement

REEDA score (3-0)

Secondary outcomes

1

Description

The severity of the pain

Timepoint

Examination from 7 days before prescribing the drug in terms of entry criteria, treatment (day zero to 4 weeks), and phase follow-up (2 and 3 months)

Method of measurement

Basal Visual analogue Scale (VAS) criterion

2

Description

Occurrence of side effects

Timepoint

At the end of the study

Method of measurement

Based on Morisky medication adherence scale

Intervention groups

1

Description

Intervention group: Patients use topical liothyronine 0.75% cream twice a day for 12 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Patients use a combination topical cream of liothyronine 0.75% and insulin 0.5% twice a day for 12 weeks.

Category

Treatment - Drugs

3

Description

Control group: Patients use Alfa cream (routine care) twice a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Center

Full name of responsible person

Fateme pasande

Street address

diabetes research center , Art Hall Alley -Azadi Square- shahid sadoughi blvd-yazd-Iran

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https://www.drinjast.com/association/diabetes_yazd_hospital/%DA%A9%D9%84%DB%8C%D9%86%DB%8C%DA%A9-%D8%AF%DB%8C%D8%A7%D8%A8%D8%AA-%DB%8C%D8%B2%D8%AF

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Fateme pasande

Position

University student

Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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