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 Saghafi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3820 3419

Email address
f.saghafi@ssu.ac.ir

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

City

Yazd

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 perior to drug administration in terms of entery 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 perior to drug administration in terms of entery 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
City
yazd
Province
Yazd
Postal code
02263728035
Phone
+98 35 3728 0226
Fax
+98 35 3728 0216
Email
drc@ssu.ac.ir
Web page address
https://www.drinjast.com/association/diabeties_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
Yazd University of Medical Sciences
Full name of responsible person
Masoud mirzaei
Street address
Bahonar Square
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3724 0171
Email

mmirzaei@ssu.ac.ir

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

Medical Pharmacy

Street address

Professor Hesabi Boulevard-Yazd-Iran

City

yazd

Province

Yazd

Postal code

8915173149

Phone

+98 35 3820 3419

Email

Pasandeelham73@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fateme saghafi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Professor Hesabi Boulevard-yazd-Iran

City

Yazd

Province

Yazd

Postal code

8915173149

Phone

+98 35 3820 3419

Email

saghafi.fa@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fateme Saghafi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Professor Hesabi Boulevard-yazd-Iran

City

Yazd

Province

Yazd

Postal code

8915173149

Phone

+98 35 3820 3419

Email

saghafi.fa@gmail.com

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