Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effects of taurine supplementation on wound healing and metabolic status in patients with diabetic foot ulcer

Protocol summary

Study aim

Determination of the effects of Taurine supplementation on wound healing, serum levels of insulin, triglyceride, total cholesterol, LDL-C, HDL-C, FBS, MDA and hsCRP in patients with diabetic foot ulcer

Design

The present study is a randomized, double-blind, and parallel clinical trial that will be performed on 50 patients with diabetic foot ulcers referred to Razi Hospital of Ahvaz who have criteria for entering the study. Patients are randomly divided into two groups.

Settings and conduct

The present study is a double-blind clinical trial with the aim of investigating the effect of Taurine on wound healing and metabolic status in patients with diabetic foot ulcers referred to Razi Hospital in Ahvaz. The investigator, physician, patient and data analyst are not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

inclusion criteria: The age range is between 18-60 years, Diabetic foot ulcer grade 3 based on Wagner-Meggitt's benchmark, More than 5 years of illness, patients with type 2 diabetes exclusion criteria: The use of alternative therapies, including hormones or vitamin supplements; Pregnant and nursing women; Patients with Chronic kidney, Liver or pulmonary diseases; ; Chronic or acute inflammatory diseases; Cardiac valve disease; Short bowel syndrome and allergy; Patients with low immune system (autoimmune)

Intervention groups

Intervention group: Taurine capsule, 1500 mg daily, 3 times per day, 500 mg capsule each time, for 30 days. Nutricost, USA. Control group: Placebo, starch, 3 times per day, 500 mg capsule each time for, 30 days. Osveh Pharma Co,Iran.

Main outcome variables

fasting insulin, triglyceride, Total Cholesterol, FBS, HDL-C, LDL-C; Length, width and depth of wound; hs-CRP, NO, GSSG

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180514039657N2**
Registration date: **2019-05-26, 1398/03/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-26, 1398/03/05**
Update count: **0**

Registration date

2019-05-26, 1398/03/05

Registrant information

Name

mahsa vahdat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8253

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vahdat.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of taurine supplementation on wound healing and metabolic status in patients with diabetic foot ulcer

Public title
Effects of taurine in diabetic foot ulcer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic foot ulcer grade 3 based on Wagner-Meggitt's benchmark More than 5 years of illness Patients with type 2 diabetes
Exclusion criteria:
The use of alternative therapies, including hormones or vitamin supplements Pregnant or lactating women Chronic kidney disease Chronic liver disease Chronic Pulmonary Disease Chronic or acute inflammatory diseases Heart valve disease Short Bowel Syndrome Allergy Patients with low immune system (autoimmune)
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Assignment of patients to each groups will be done by random block method using block of size 6. Random numbers will be generated randomly by random allocation software. In order to ensure that the selection bias does not occur, the allocation method will be used to allocate a unique code to each patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this double blind study the jars containing the capsules will be the same and neither the patients nor researchers know which capsules are being received. In fact, a third person who knows the contents of the jars distributes them among the participants. The shape and size of the capsules are similar in both groups, while their content is different.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2019-04-13, 1398/01/24
Ethics committee reference number
IR.AJUMS.REC.1398.021

Health conditions studied

1

Description of health condition studied
Diabetic Foot Ulcer
ICD-10 code
E10, E11
ICD-10 code description
Diabetic ulcer

Primary outcomes

1

Description
fasting insulin
Timepoint
The beginning and end of the study
Method of measurement
ELISA

2

Description
serum triglyceride
Timepoint
The beginning and end of the study
Method of measurement
enzymatic method

3

Description
total cholesterol

Timepoint
The beginning and end of the study
Method of measurement
enzymatic method

4

Description
LDL-C
Timepoint
The beginning and end of the study
Method of measurement
enzymatic method

5

Description
HDL-C
Timepoint
The beginning and end of the study
Method of measurement
enzymatic method

6

Description
Fasting Blood Glucose
Timepoint
The beginning and end of the study
Method of measurement
enzymatic method

7

Description
hs-CRP
Timepoint
The beginning and end of the study
Method of measurement
ELISA

8

Description
fructosamine
Timepoint
The beginning and end of the study
Method of measurement
enzymatic method

9

Description
Nitric Oxide
Timepoint
The beginning and end of the study
Method of measurement
Spectrophotometry

10

Description
Oxidized glutathione
Timepoint
The beginning and end of the study
Method of measurement
Spectrophotometry

11

Description
Wound healing
Timepoint
The beginning and end of the study
Method of measurement
Wagner-Meggitt's classification

Secondary outcomes

1

Description
weight
Timepoint
The beginning and end of the study
Method of measurement
scale

2

Description
Body Mass Index
Timepoint
The beginning and end of the study
Method of measurement
weight (kg) divided to height square

3

Description
Systolic Blood Pressure
Timepoint
The beginning and end of the study
Method of measurement
Measuring blood pressure

4

Description
Diastolic Blood Pressure
Timepoint
The beginning and end of the study
Method of measurement
Measuring blood pressure

Intervention groups

1

Description
Intervention group: 25 patients with diabetic foot ulcers take one 500 mg thorium capsule three times per day (1500 mg daily) for 30 days. To control the correct use of pills, cans are available to patients every two weeks and the number of capsules consumed.
Category

Treatment - Drugs

2

Description
Control group: 25 diabetic foot ulcers use a 500 mg starch capsule three times per day (1500 mg daily) for 30 days. To control the correct use of capsules, cans are available to patients every two weeks and the number of capsules consumed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Razi Hospital
Full name of responsible person
Dr. Arman Shahriari
Street address
Razi Hospital, Palestine Street, Amanayeah, Ahvaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
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Vice Chancellor for Research and Technology,Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Masih Namjoonia
Position
BSc of nutrition
Latest degree
Bachelor
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person

Mahsa Vahdat

Position

Msc Student

Latest degree

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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