Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
Email address
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
City
Ahvaz
Province
Khouzestan
Postal code
6196514941
Phone
+98 61 3333 3050
Email
shahriari-a@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
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
Phone
+98 61 3336 7570
Email
badavi-m@ajums.ac.ir
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
Other areas of specialty/work
Nutrition
Street address
Amaniyeh - Palestine Street - Razi Hospital
City
Ahvaz
Province
Khouzestan
Postal code
6196514941
Phone
+98 61 3333 3050
Email
masih.namjoo@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Arman Shahriari
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Amaniyeh - Palestine Street - Razi Hospital
City
Ahvaz
Province
Khouzestan
Postal code

6196514941

Phone
+98 61 3333 3050

Email
shahriari-a@ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mahsa Vahdat

Position
Msc Student

Latest degree
Bachelor

Other areas of specialty/work
Nutrition

Street address
Faculty of Paramedicine, Jundishapur University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
6135815751

Phone
+98 61 3321 4578

Email
vahdat.m@ajums.ac.ir

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