Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

The assessment of the effect of L-carnitine supplementation versus placebo on serum total antioxidant and oxidant capacities, lipid profile in patients with pemphigus vulgaris

Protocol summary

Summary

This study will be done as a double blind placebo controlled clinical trial on 52 patients with 30 to 65 years old affected by pemphigus vulgaris. The patients presenting to RAZI hospital who affected to the illness at least one year and using Prednisolone will be under study in order to determine the influences of L-carnitine supplementation to the total antioxidant and oxidative capacities, serum lipid profiles, psychological status, fatigue and quality of life. Patients will be divided in two groups according to permuted block randomization by using random code receive 1000 mg of L-carnitine or placebo tablets twice a day. The duration of this intervention is 8 weeks; at the beginning and end of the study, 10 cc blood will be taken from patients for measuring the serum concentration of fasting blood glucose, triglycerides, total cholesterol, HDL, LDL, VLDL, TAC, TOC, F2isoprostane and L-carnitine. The dietary data of the patients also will be collected by a 24-h dietary recall for three days (one holiday day and two usual days) at the beginning and end of the study. Also SF-36, GHQ-12, FSS and DLQI questionare will be taken at the beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062322769N4**
Registration date: **2015-08-13, 1394/05/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-08-13, 1394/05/22

Registrant information

Name
Mohammad Hassan Javanbakht
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 21 8891 4462
Email address
mhjavan@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of medical sciences; school of nutritional sciences and dietetics

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-09, 1394/12/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of the effect of L-carnitine supplementation versus placebo on serum total antioxidant and oxidant capacities, lipid profile in patients with pemphigus vulgaris

Public title

The effect of L-carnitine in the treatment of complications of patients with pemphigus vulgaris

Purpose

Prevention

Inclusion/Exclusion criteria
INCLUSION CRITERIA: Willingness to cooperate; Affected by pemphigus vulgaris; Minimum one year of pemphigus vulgaris illness; Using Corticosteroid alone or with one of the Methotrexate, Azathioprine and Cellcept drugs; Age between 30 and 65 years old; BMI<35; Lack of Cardiovascular disease, renal, hepatic and inflammatory intestinal diseases; No alcohol consumption; Do not use of any antioxidant supplementation during the last 3 months; No consumption of Cisplatin, Theophylline and Valproate during the past month; Non-smoking and tobacco use (People who have smoked less than five cigarettes daily in previous 6 months); Lack of pregnancy and lactation EXCLUSION CRITERIA: Changing the type of used drug; Find allergy symptoms at any time of the study

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
For double blinding the study, all boxes of l-carnitine and placebo tablets will be divided in two groups of 1 and 2 by someone other than researcher. The researcher, physician and the patient will be unaware of this group division. This group division will be done based on a random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Sixth Floor, Central department of University, Ghods St., Keshavarz Blvd.

City
tehran

Postal code

Approval date
2015-06-14, 1394/03/24

Ethics committee reference number
IR.TUMS.REC.1394.28

Health conditions studied

1

Description of health condition studied
pemphigus vulgaris

ICD-10 code
L10.0

ICD-10 code description
Pemphigus vulgaris

Primary outcomes

1

Description
L-carnitine

Timepoint
Before and 8 weeks after intervention

Method of measurement
Through the serum by ELISA kit

2

Description
Osteopentin

Timepoint
Before and 8 weeks after intervention

Method of measurement
Through the serum by ELISA kit

3

Description
Total oxidant capacity

Timepoint
Before and 8 weeks after intervention

Method of measurement
Through the serum by ELISA kit

4

Description
F2isoprostane

Timepoint
Before and 8 weeks after intervention

Method of measurement
Through the serum by ELISA kit

5

Description
Total cholesterol

Timepoint
Before and 8 weeks after intervention

Method of measurement
Through the serum by colorimetric

6

Description
Triglycerides
Timepoint
Before and 8 weeks after intervention
Method of measurement
Through the serum by colorimetric

7

Description
Low-density lipoprotein
Timepoint
Before and 8 weeks after intervention
Method of measurement
Through the serum by colorimetric

8

Description
High-density lipoprotein
Timepoint
Before and 8 weeks after intervention
Method of measurement
Through the serum by colorimetric

9

Description
Fasting Blood sugar
Timepoint
Before and 8 weeks after intervention
Method of measurement
Through the serum by colorimetric

10

Description
Added at 2017-08-08:bone morphogenic protein 4
Timepoint
Added at 2017-08-08: Before and 8 weeks after intervention
Method of measurement
Added at 2017-08-08: Through the serum by ELISA kit

11

Description
Added at 2017-08-08: cystatin c
Timepoint
Added at 2017-08-08: Before and 8 weeks after intervention
Method of measurement
Added at 2017-08-08: Through the serum by ELISA kit

12

Description
Added at 2017-10-05: HOMA-IR
Timepoint
Added at 2017-10-05: Before and 8 weeks after intervention
Method of measurement
Added at 2017-10-05: Serum concentration using ELISA kit

13

Description
Added at 2017-10-05: SFRP5
Timepoint
Added at 2017-10-05: Before and 8 weeks after intervention
Method of measurement
Added at 2017-10-05: Serum concentration using ELISA kit

14

Description
Added at 2017-10-05: Visfatin
Timepoint
Added at 2017-10-05: Before and 8 weeks after intervention
Method of measurement
Added at 2017-10-05: Serum concentration using ELISA kit

15

Description
Added at 2017-10-05: Omentin
Timepoint
Added at 2017-10-05: Before and 8 weeks after intervention
Method of measurement
Added at 2017-10-05: Serum concentration using ELISA kit

Secondary outcomes

1

Description
Quality of life
Timepoint
at the beginning and at the end of the study
Method of measurement
SF-36, GHQ-12, FSS and DLQI questionares

2

Description
Added at 2017-10-05: QUICKI
Timepoint
Added at 2017-10-05: Before and 8 weeks after intervention
Method of measurement
Added at 2017-10-05: Serum concentration using ELISA kit

3

Description
Added at 2017-10-05: Insulin
Timepoint

Added at 2017-10-05: Before and 8 weeks after intervention

Method of measurement

Added at 2017-10-05: Serum concentration using ELISA kit

Intervention groups

1

Description

The use of pill type L-carnitine supplement produced by KAREN chemistry company in 1000 mg dose twice a day (morning and evening) for 8 weeks

Category

Treatment - Drugs

2

Description

The use of pill type placebo produced by KAREN chemistry company in 1000 mg dose twice a day (morning and evening) for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Razi skin

Full name of responsible person

Mohamad Hasan Javanbakht/PHD Nutrition/Assistant Professor and Faculty member of School of Nutrition

Street address

HAFEZ St., VAHDAT ESLAMI Ave., VAHDAT ESLAMI Sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Masud Yunesian

Street address

Sixth Floor, Central department of University, Ghods St., Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hasan Javanbakht

Position

PHD Nutrition/Assistant Professor and Faculty member of School of Nutritional Sciences and Dietetics

Other areas of specialty/work

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City

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Postal code

Phone

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mhjavan2001@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hasan Javanbakht

Position

PHD Nutrition

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

Full name of responsible person
Mohammad Hasan Javanbakht

Position
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty