

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

The effect of L carnitine on clinical symptoms, lipid profile and oxidative stress in obese women with knee osteo arthritis under weight loss diet

Protocol summary

Summary

In this study, the effects of L carnitine on clinical symptoms, lipid profile and oxidative stress in women with osteoarthritis, was investigated. The design of study is a double-blind randomized clinical trial. In this clinical trial, 76 women with osteoarthritis will be randomly assigned to 2 groups by using the table of random numbers: 1) Consuming one tablet 1000 mg L carnitine AND weight loss diet 2) Consuming one tablet placebo with weight loss diet. Inclusion criteria will include women between 45- 70 years, body mass index(BMI) more than 25 and exclusion criteria will include disease such as heart disease, hypothyroidism, rheumatoid arthritis , hepatic disease, kidney disease. Participants will be followed up for 12 weeks. Total cholesterol, triglyceride, high density lipoprotein cholesterol, C reactive protein(CRP), Malondialdehyde (MDA), weight, height, fat mass, fat free mass, waist, Hip circumference, Western Ontario and McMaster Universities Arthritis Index(WOMAC)(for pain) will be measured at the baseline and at the end of the trial. Low density lipoprotein level will be calculated by the Friedewald's formula.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011932026N2**

Registration date: **2017-04-27, 1396/02/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-27, 1396/02/07

Registrant information

Name

Mahdie Hoseinzade

Name of organization / entity

Shahid Sadoughi University Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 9110

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hoseinzadeh@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Science

Expected recruitment start date

2017-01-29, 1395/11/10

Expected recruitment end date

2017-05-31, 1396/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of L carnitine on clinical symptoms, lipid profile and oxidative stress in obese women with knee osteo arthritis under weight loss diet

Public title

The effect of L carnitine in women with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: women: age between 45 to 70: Early detection of osteoarthritis: body mass index more than25: Lack of weight loss diets over the past three months: lack of participate in the intervention program

the past three months Exclusion: heart disease:
hypothyroidism: rheumatoid arthritis: hepatic
disease: kidney disease and knee surgery

Age

From **45 years** old to **70 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

in this study will be randomly assigned to 2 groups by
using the table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of School of Public Health, Shahid
Sadoughi University of Medical Sciences,

Street address

Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran

City

Yazd

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.SSU.SPH.REC.1395.45

Health conditions studied

1

Description of health condition studied

knee osteo arthritis

ICD-10 code

M15.0

ICD-10 code description

Primary generalized (osteo)arthrosis

Primary outcomes

1

Description

pain

Timepoint

before intervention and 12 weeks after the intervention

Method of measurement

womac questionnaire

2

Description

lipid profile(HDL, LDL, TG, Cho)

Timepoint

before intervention and 12 weeks after the intervention

Method of measurement

with special kits

3

Description

CRP

Timepoint

before intervention and 12 weeks after the intervention

Method of measurement

with special kits

4

Description

Malondialdehyde

Timepoint

before intervention and 12 weeks after the intervention

Method of measurement

with special kits

Secondary outcomes

1

Description

waist, Hip circumference.

Timepoint

before intervention and 12 weeks after the intervention

Method of measurement

meter

2

Description

weight, fat mass, free fat mass

Timepoint

before intervention and 12 weeks after the intervention

Method of measurement

Omron digital Scale(BF11)

Intervention groups

1

Description

control group:this group will consume of one tablet(1000mg placebo) one time a day after meals (lunch or breakfast) with weight loss diet for 12 weeks. tablets will produce from Karen Company in Yazd.

Category

Treatment - Drugs

2

Description

intervention group:this group will consume of one tablet(1000mg L carnitine) one time a day after meals (lunch or breakfast) with weight loss diet for 12 weeks. tablets will produce from Karen Company in Yazd.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al-Anbia Super Speciality Clinic

Full name of responsible person

Dr.Ali Dehghan

Street address

Taleghani Street, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of School of Public Health, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Seyed Saeid Mazloomi

Street address

Shohaday-e-Gomnam Blvd., Alem Sq., Yazd, Iran

City

Yazd

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 of School of Public Health, Shahid Sadoughi 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 Public Health, Shahid Sadoughi University of Medical Sciences,

Full name of responsible person

Farnaz Baghban

Position

master of nutrition/graduate student of Health Sciences in NutritionG

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Public Health, Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Mahdie Hoseinzadeh

Position

Assistant Professor/Phd of nutrition

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

School of Public Health, Shahid Sadoughi University of
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Full name of responsible person

Dr. Hassan Mozaffari Khosravi

Position

PhD of nutrition science/ Profesor

Other areas of specialty/work

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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