Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of L carnitine on clinical symptoms, lipid profile and oxidative stress in obese women with knee osteo arthiritis 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
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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 arthiritis 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 sergury

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 Scien

Full name of responsible person
Dr Seyed Saeid Mazloomy

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 Scien

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

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Name of organization / entity
School of Public Health, Shahid Sadoughi University of Medical Sciences

Full name of responsible person
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Assistant Professor/Phd of nutritin

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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