

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Assessing effect of L-carnitine supplementation on nutritional status, serum inflammatory and oxidative stress factors, matrix metalloproteinase enzymes and clinical symptoms of females with knee osteoarthritis

Protocol summary

Summary

(1)Objectives: Effect of L-carnitine supplementation in comparison with placebo on nutritional status, serum inflammatory and oxidative stress factors, matrix metalloproteinase enzymes and clinical symptoms of females with knee osteoarthritis (2)Design: Double blind randomized clinical trial (3)Setting and conduct: 72 volunteer female patients with bilateral primary osteoarthritis of knee who receive the same and standard pharmaceutical treatments, will be randomly divided into two groups intervention (L-carnitine) and control (placebo). (4)Participants including major eligibility criteria: volunteer female patients with bilateral primary osteoarthritis of knee aged 40-60 years old and body mass index of 25-35; Using glucoseamine & chondroitin sulphate supplements and acetaminophene as anti-pain drug; Patient tendency and ability to participate in the study. (5)Intervention: Intervention group: 750 mg/day L-carnitine as 3 tablets of 250 mg and control group: placebo as 3 tablets per day for 8 weeks. (6) Main outcome measures: Clinical symptoms including pain, joint stiffness and disability; Nutritional status; Inflammatory factors including hs-CRP & Interleukin-1 β (IL-1 β); Oxidative factors including malondialdehyde(MDA) & total antioxidant capacity(TAC); Matrix metalloproteinase-1(MMP-1) and Matrix metalloproteinase-13 (MMP-13)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311231197N17**
Registration date: **2013-11-26, 1392/09/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-11-26, 1392/09/05

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences - Nutrition Research Center

Expected recruitment start date

2013-12-01, 1392/09/10

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing effect of L-carnitine supplementation on nutritional status, serum inflammatory and oxidative stress factors, matrix metalloproteinase enzymes and

clinical symptoms of females with knee osteoarthritis

Public title

Assessing effect of L-carnitine supplementation on nutritional status, serum inflammatory and oxidative stress factors, matrix metalloproteinase enzymes and clinical symptoms of females with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Female; Age: 40-60 years; Bilateral primary osteoarthritis of knee (according to ACR classification); Body mass index of 25-35; Using glucoseamine & chondrotin sulphate supplements and acetaminophene as anti-pain drug; Patient tendency and ability to participate in the study. Exclusion criteria: Severe osteoarthritis; Secondary osteoarthritis; Active synovitis; Having a history of knee injection during the past 6 months; Neurological disorder that affects movement, muscle control and balance; Uncontrolled hypertension, diabetes, cardiovascular disorders, chronic kidney disorders and functional liver disorders; Using Furosemide, Probenecid, Anticoagulants, Anticonvulsant, Sulphonamides, Methotrexate, Lithium salts and muscle relaxants; Using antioxidant supplements and w3; Smoking; History of allergy; Pregnancy and or lactation.

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization is performed by permuted block randomization (block size: 4) using RAS software.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Golgasht street- Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

2013-11-18, 1392/08/27

Ethics committee reference number

92127

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description

pain

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

WOMAC questionnaire

2

Description

joint stiffness

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

WOMAC questionnaire

3

Description

diability

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

WOMAC questionnaire

Secondary outcomes

1

Description

Serum inflammatory factors

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

IL-1 β and hs-CRP

2

Description

Serum oxidative factors

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Malondialdehyde and total antioxidant capacity

3

Description

Serum matrix metalloproteinases

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

matrix metalloproteinase-1 and matrix metalloproteinase-13

4

Description

Nutritional status and dietary intake

Timepoint

Before the intervention and 2 months after the intervention

Method of measurement

Dietary intake: 24 hours food recall questionnaire;
Nutritional status: Weight: Standard scale, Height: Stadiometer

Intervention groups

1

Description

Intervention group: L-carnitine 250 mg (made by Karen pharmaceutical and nutritional supplements manufacture), 3 tablets a day for 8 weeks

Category

Treatment - Other

2

Description

Control group: placebo 3 tablets a day for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golgasht clinic

Full name of responsible person

Dr. Susan Kolahi

Street address

Azadi Street, Shafa Alley

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Rashidi

Street address

Golgasht Street -Tabriz University of Medical Sciences

City

Tabriz

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 Tabriz University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Nutrition Research Center, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Alireza Ostadrahimi

Street address

Golgasht Street, Attar neishaboori Avenue, Nutrition Research Center, Tabriz University of Medical Sciences

City

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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

Nutrition Research Center, Tabriz University of Medical Sciences

Proportion provided by this source**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**

Faculty of Nutrition, Tabriz University of Medical Sciences

Full name of responsible person

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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