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 pharmaucetical 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 & chondrotin 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 icluding pain, joint stiffness and disability; Nutritional status; Inflammatory factors including hs-CRP & Interleukin-1β(IL-1β); 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

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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-1β and hs-CRP

2

Description
Serum oxidative factors
Timepoint
Before the intervention and 2 months after the intervention
Method of measurement
Malondialdehide 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
Tabriz
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

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Name of organization / entity
Faculty of Nutrition, Tabriz University of Medical Sciences
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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