

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of garlic supplementation on body composition and knee pain in postmenopausal overweight and obese women with knee osteoarthritis

Protocol summary

Summary

For several years garlic has been used for herbal in treatment of several disease. However, its efficacy in the treatment of this disease has not demonstrate yet. In this double blind study we investigate the effect of 12 weeks supplementation with garlic on body composition and severity of pain in patients with knee osteoarthritis. We investigated on 80 postmenopausal women with knee osteoarthritis. Subjects were randomly divided into two groups, they will take 500 mg garlic tablet or its placebo twice a day for 3 months. In every month, weight, height, waist and hip circumferences will measure. Before and after 12 weeks of intervention % fat and fat free mass with BIA will measure. In addition, pain and other symptoms will be assessed monthly by WOMAC questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307179543N2**

Registration date: **2013-09-11, 1392/06/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-09-11, 1392/06/20

Registrant information

Name

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Name of organization / entity

Tehran University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences

Expected recruitment start date

2012-05-30, 1391/03/10

Expected recruitment end date

2012-06-30, 1391/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of garlic supplementation on body composition and knee pain in postmenopausal overweight and obese women with knee osteoarthritis

Public title

The effect of garlic on knee joint pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterias: female, 50-75 years old, $25 \leq \text{BMI} \leq 35$, mild or moderate osteoarthritis. Exclusion criteria: severe pain or hip involvement; candidate for surgery; had a knee surgery; sensitivity of garlic; smoking; history of cardiovascular disease; type 1 diabetes; liver disease; hypo or hyper thyroid; kidney disease; arthritis; gout; cancer; any injection in knee in 3 month before intervention; intake of NSAIDs; HRT; astatine; warfarin and supplement like omega 3 or 6 and chondroitin sulphate; being in a diet or weight loss about 5% during 3 month in this study.

Age

From **50 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Central Organization Of Tehran University Of Medical Sciences

Street address

Central Organization Of Tehran University Of Medical Sciences, keshavarz ave, ghods ave

City

Tehran

Postal code

Approval date

2012-05-08, 1391/02/19

Ethics committee reference number

130/2783/90/3

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Gonarthrosis (arthritis of knee)

Primary outcomes

1

Description

Pain of knee based on "WOMAC" questionnaire

Timepoint

3 months

Method of measurement

"WOMAC" questionnaire

Secondary outcomes

1

Description

body composition

Timepoint

3 months

Method of measurement

bioelectrical impedance analysis

2

Description

Added at 2017-07-15: WOMAC physical function subscale score

Timepoint

Added at 2017-07-15: 12 weeks

Method of measurement

Added at 2017-07-15: questionnaire

Intervention groups

1

Description

1)drug: 500mg garlic tablet twice a day2)

Category

Treatment - Drugs

2

Description

placebo: 500 mg lactose twice a day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. Ahmad Salimzadeh

Street address

30 Tir street, Emam khomeini street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Uuniversity Of Medical Science

Full name of responsible person

Dr.Mohammad Javad Hosseini Atar

Street address

Ghods ave, Keshavarz ave.

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran Uuniversity Of Medical Science

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**

Tehran University Of Medical Science

Full name of responsible person

Sahar Dehghani

Position

student in Master of Science

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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*