

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of garlic supplementation on serum levels of resistin, tumor necrosis factor- α in post menopause overweight and obese women with knee osteoarthritis

Protocol summary

Summary

This study is a double-blind clinical trial that will be carried out for 3 months on 80 postmenopausal obese women (75-50 years), with knee osteoarthritis who were referred to Sina Hospital Clinic. at first the disease in people with knee osteoarthritis is diagnosed by a rheumatologist and if there is no exclusion criteria include:severe pain or hip involvement; candidate for surgery; sensitivity of garlic; smoking; history of cardiovascular disease; type 1 diabetes; liver disease; hypo or hyper thyroid; arthritis,women will be include in this study. Women will be randomly divided into two groups: 40 patients in the intervention group received 500 mg garlic supplements, two times a day and another 40 women in the control group, will receive 500 mg placebo. Blood samples from each of the participants at the beginning and end of project will be compare(In order to evaluate and compare the inflammatory factors such as tumor necrosis factor-alpha and serum Resistin and fasting blood sugar). Patients monthly in terms of dietary intake of macronutrients and micronutrients (through questionnaires during 24 hours recall), physical activity (via questionnaires international Matt), weight, body composition (percent fat and fat free mass using the BIA) , height and BMI will be checked. all information will be saved in spss v.19.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204239543N1**
Registration date: **2012-06-10, 1391/03/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-10, 1391/03/21

Registrant information

Name

Sahar Dehghani

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

Effects of garlic supplementation on serum levels of resistin, tumor necrosis factor- α in post menopause overweight and obese women with knee osteoarthritis

Public title

Effect Of Garlic In Knee osteoarthrosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: women; 50-75 years old; postmenopausal; obese body mass index between 25 - 35 with moderate and severe knee osteoarthritis
Diagnosis by rheumatologist. 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 University, 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 [arthrosis of knee]

Primary outcomes

1

Description

Resistin

Timepoint

Week 12

Method of measurement

Lab kit

2

Description

Tumor Necrosis Factor-Alpha

Timepoint

Week 12

Method of measurement

kit

Secondary outcomes

1

Description

Body Composition (Fat mass, Fat Free Mass)

Timepoint

Week 12

Method of measurement

Bio Electrical Impedance

2

Description

Fasting Blood Sugar

Timepoint

Week 12

Method of measurement

ELISA kit

3

Description

Weight

Timepoint

Week 12

Method of measurement

Balance

Intervention groups

1

Description

Drug (Garlic tablet 500 Mg, Twice a day for 3 month)

Category

Treatment - Drugs

2

Description

Placebo twice a day for 3 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr.Ahmad Salimzadeh

Street address

Sina Hospital, Emam khomeyni Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University Of Medical Sciences

Full name of responsible person

Dr.Mohammad Javad Hosseinzadeh

Street address

Tehran University Of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University Of Medical Sciences

Full name of responsible person

Sahar Dehghani

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Position

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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