

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of the effect of green tea extracts in patients with mild to moderate knee osteoarthritis

Protocol summary

Summary

Goals: Osteoarthritis (OA) is a progressive, degenerative joint disease that has a major impact on joint function and quality of life. Green tea has been being used in traditional medicine and there are some evidences that this herb, especially one of its derivatives, epigallocatechin 3-gallate (EGCG), may have a role in inflammation and joint destruction. As there is no clinical study regarding the effects of either green tea or EGCG on OA, in this study we assumed to review its clinical effects in patients suffering OA. Design: An Interventional study Participants: Forty patients were enrolled into this randomized clinical trial. They were divided into two groups, cases and controls. Inclusion criteria: patients of both sexes with mild to moderate osteoarthritis of the knee, in the age group 40 to 75 years, referred to the Physical Medicine and Rehabilitation, Shiraz, Iran. Exclusion criteria: patients with severe osteoarthritis; patients suffering ischemic heart disease or heart failure; patients with renal function impairment; patients with hepatic failure; pregnant women; breastfeeding women; women who stop contraception techniques to become pregnant; patients who had a history of sensitivity to caffeine; patients whose diets are effective for weight loss or gain, and planned to decrease or increase their weight; patients who have recently begun the exercise to protect joints or changing their activity levels; patients treated with alkaline agents, for any reason, who was not able to discontinue their medications; patients treated with warfarin for any reason, that the patient was unable to stop his warfarin; patients with a history of gastrointestinal bleeding with non-steroidal anti-inflammatory drugs; patients who for any reason were not able to express their pain (eg patients with mental retardation or patients with Alzheimer's); patients who did not receive the necessary support for their drugs or they are not likely to be followed (eg, patients who were residents of older people centers); patients who do not continue the trial: intolerable side effects for the patient

(Gastrointestinal side effects such as increased gastric acid secretion, diarrhea or constipation, headache, palpitations, insomnia, irritability, restlessness);discontinuation of drugs consumption for any reason and not to follow treatment for any reason. Intervention: At the beginning of the study, WOMAC questionnaire were completed for each patient. Then, cases received 1500 mg/day of green tea leaves plus 100 mg/day diclofenac, while the controls consumed only 100 mg/day diclofenac. Outcome : After one month, they were evaluated again, using the WOMAC questionnaire. Key word: Osteoarthritis, Green tea, Epigallocatechin 3-gallate

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307188300N2**
Registration date: **2013-11-05, 1392/08/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-11-05, 1392/08/14

Registrant information

Name

Alireza Ashraf

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1231 9040

Email address

ashrafa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Science- School of Medicine

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of green tea extracts in patients with mild to moderate knee osteoarthritis

Public title

Evaluation of the effect of green tea extracts in osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients of both sexes with mild to moderate osteoarthritis of the knee, in the age group 40 to 75 years, referred to the Physical Medicine and Rehabilitation, Shiraz, Iran. Exclusion criteria: patients with severe osteoarthritis; patients suffering ischemic heart disease or heart failure; patients with renal function impairment; patients with hepatic failure; pregnant women; breastfeeding women; women who stop contraception techniques to become pregnant; patients who had a history of sensitivity to caffeine; patients whose diets are effective for weight loss or gain, and planned to decrease or increase their weight; patients who have recently begun the exercise to protect joints or changing their activity levels; patients treated with alkaline agents, for any reason, who was not able to discontinue their medications; patients treated with warfarin for any reason, that the patient was unable to stop his warfarin; patients with a history of gastrointestinal bleeding with non-steroidal anti-inflammatory drugs; patients who for any reason were not able to express their pain (eg patients with mental retardation or patients with Alzheimer's); patients who did not receive the necessary support for their drugs or they are not likely to be followed (eg, patients who were residents of older people centers); patients who do not continue the trial: intolerable side effects for the patient (Gastrointestinal side effects such as increased gastric acid secretion, diarrhea or constipation, headache, palpitations, insomnia, irritability, restlessness); discontinuation of drugs consumption for any reason and not to follow treatment for any reason.

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz university of medical science

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

3271

Health conditions studied**1****Description of health condition studied**

Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

Primary outcomes**1****Description**

Function

Timepoint

at the beginning and 1 month after intervention

Method of measurement

WOMAC questionnaire

2**Description**

Pain

Timepoint

at the beginning and 1 month after intervention

Method of measurement

WOMAC questionnaire

3

Description

Joint stiffness

Timepoint

at the beginning and 1 month after intervention

Method of measurement

WOMAC questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

cases received 1500 mg/day of green tea leaves in 3 doses(Dineh Company with certification number:1228144011) plus 100 mg/day diclofenac

Category

Treatment - Drugs

2

Description

control group: 100 mg Diclofenac

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinic

Full name of responsible person

Dr Alireza Ashraf

Street address

Namazi Square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.gholamreza Hatam

Street address

Imam Hossein square

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

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Position

Medical Student

Other areas of specialty/work

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Shiraz university of medical sciences

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Dr.Alireza Ashraf

Position

Associate Professor

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Faghihi hospital,Zand avenue

City

Shiraz

Postal code**Phone**

+98 71 1231 9040

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