

# 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**

Sara Sadrneshin

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

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**Position**

Specialist in Physical Medicine and Rehabilitation

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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Associate Professor

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Faghihi hospital,Zand avenue

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**Postal code****Phone**

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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*