Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Ginger extract on pain and physical examination finding in knee Osteoarthritis

Protocol summary

Summary

Osteoarthritis is the most common joint disease. (1) Objectives: This project is on the effect of ginger effective, safe and affordable in patients with osteoarthritis knee pain achieve (2) Design: evaluation of the clinical trial is double blind. (3) How to do: observing patients in the study, randomly selected. During the six month period, drug or placebo was given (4) Participants and conditions of entry and exit: in part, was expressed. (5) Interventions: prescription drug or placebo. (6) The main outcome variables: Indices of pain (Visual Analog scale, Lequesne's pain, and VOMAC), physical findings, patient and physician global assessment and possible side effects of drugs. (7) Results: Severity of symptoms at each visit using the variables studied, were recorded. Patient information in the database were collected and analyzed. Detailed results with respect to drug and placebo when combined with other managing systems were used in these patients. Respect to detailed results; substantial and statistically significant effect on pain is seen in drug group that more prominent in first couple of weeks. Changes in physical examination results are given in detail in the text.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111088034N1**
Registration date: **2012-12-03, 1391/09/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-12-03, 1391/09/13

Registrant information

Name

Ahmad Salimzadeh

Name of organization / entity

Tehran University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6634 8500

Email address

salimzad@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of medical sciences, Vice chancellor for research

Expected recruitment start date

2004-04-20, 1383/02/01

Expected recruitment end date

2011-11-22, 1390/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ginger extract on pain and physical examination finding in knee Osteoarthritis

Public title

Ginger effect on pain in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria; knee pain and osteophyte in knee radiography; and at least one criterion of the three following criteria: 50 years age; Morning stiffness of less than 30 minutes; Crepitus in motion. Exclusion criteria: The history of rheumatoid arthritis, gout,

chondrocalcinosis; severe and advanced cardiovascular disease class 4; proven malignancy; there is significant liver disease (esophageal varices and bleeding, encephalopathy, ascites); severe renal disease (creatinine greater than 3 mg dL); pregnancy and lactation; received intra-articular drug in former three months (or wait until this time period be spent); Glucosamine or Piascledine receive more than 2 weeks during the past six months; concomitant hip osteoarthritis

Age
From **50 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **140**

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
Medical ethtics of Tehran University of medical sciences

Street address
Keshavarz Blvd

City
Tehran

Postal code

Approval date
2004-12-23, 1383/10/03

Ethics committee reference number
7559/132

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M17.0

ICD-10 code description
Primary gonarthrosis, bilateral

Primary outcomes

1

Description
Knee pain

Timepoint
6 week

Method of measurement
VAS, Lequensnes Pain Index Of Severity For OA Of The Knee, VOMAC

Secondary outcomes

1

Description
Joint crepitus

Timepoint
6 month

Method of measurement
physical exam

2

Description
Patient global assessment

Timepoint
Each 6 weeks

Method of measurement
Interview

3

Description
Physician global assessment

Timepoint
Each 6 weeks

Method of measurement
Questionnaire

4

Description
Drug side effect

Timepoint
Each 6 weeks

Method of measurement
Interview

Intervention groups

1

Description
The drug is extracted from ginger and packed as gelatinous capsule. Each capsule contains 1 gram of ginger extract that equal to 3 gram of crude plant. The

patient must be taken 3 capsules by meal in divided dose.

Category

Treatment - Drugs

2

Description

The placebo is made from same capsule but is filled by starch.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Ahmad Salimzadeh

Street address

Emam Khomeini Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of medical sciences, Vice chancellor for research

Full name of responsible person

Dr Akbar Fotoohi

Street address

Keshavarz Blvd.

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, Vice chancellor for research

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, Sina Hospital

Full name of responsible person

Dr Ahmad Salimzadeh

Position

Associate professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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