

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

analgesic and anti-inflammatory effect of syrup g-rup (ginger and honey) in knee osteoarthritis

Protocol summary

Summary

The goal of this study is to evaluate the efficacy of ginger syrup (G-rup) in the treatment of knee osteoarthritis. Inclusion criteria include moderate to severe knee pain due to osteoarthritis, and 40 to 85 years of age. Diabetes mellitus, and renal and hepatic diseases are among the exclusion criteria. In a double-blind randomized clinical trial, 42 patients with knee osteoarthritis presenting to pain clinic of Amir Alam and Shariati hospitals, Tehran, will be assigned into 2 groups. One group will receive 10 ml of G-rup syrup (ginger syrup containing 100 mg/ml ginger extract and 150 mg/ml honey extract) 3 times a day, and the other group (as control) will receive 10 ml of placebo syrup (containing 150 mg/ml honey extract, sorbitol, and ginger essence) 3 times per day for 12 weeks. All the patients will be allowed to continue their previously prescribed medications (calcium, vitamin D and benzodiazepines) as recommended by their physicians. The non-steroidal anti-inflammatory drugs shall be discontinued from one week before until the end of the study, but if the patients need analgesic medications they will be able to use acetaminophen (at maximum daily dose of 3 g). The patients' pain and functional capacity score will be assessed by Numerical Rating Scale (NRS 0-10) and The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at the beginning of the study and at 4, 8, and 12 weeks thereafter.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091924083N1**

Registration date: **2016-01-22, 1394/11/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-22, 1394/11/02

Registrant information

Name

Alireza Khajehnasiri

Name of organization / entity

Shariati Hospital/Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0000

Email address

khajehnasiri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Pharmaceutical Sciences University

Expected recruitment start date

2015-10-10, 1394/07/18

Expected recruitment end date

2015-12-30, 1394/10/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

analgesic and anti-inflammatory effect of syrup g-rup (ginger and honey) in knee osteoarthritis

Public title

analgesic and anti-inflammatory effect of syrup g-rup (ginger and honey) in knee osteoarthritis

Purpose

Treatment
Inclusion/Exclusion criteria
Inclusion criteria: moderate to severe knee pain due to osteoarthritis , aged 40-85 years
Exclusion criteria: Diabetes mellitus, renal and hepatic diseases, coagulation disorders, mental and psychological disorders, and intolerance or allergy to any of components of the two syrups

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

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

Ethics Committee Islamic Azad University,
Pharmaceutical Sciences Branch

Street address

No 99, Yasaman Street, Shariati Street

City

Tehran

Postal code

Approval date

2015-09-22, 1394/06/31

Ethics committee reference number

IR.IAU.PS.REC.1394.28

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M17.0; M17

ICD-10 code description

Primary gonarthrosis, bilateral; Other primary gonarthrosis

Primary outcomes

1

Description

Pain

Timepoint

at the beginning of the study and at 4, 8, and 12 weeks thereafter

Method of measurement

Numerical Rating Scale (NRS 0-10)

Secondary outcomes

1

Description

functional capacity

Timepoint

at the beginning of the study and at 4, 8, and 12 weeks thereafter

Method of measurement

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Intervention groups

1

Description

Intervention with placebo syrup (containing 150 mg/ml honey extract, sorbitol, and ginger essence) 10 ml, 3 times per day for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention with medication: 10 ml of G-rup syrup (ginger syrup containing 100 mg/ml ginger extract and 150 mg/ml honey extract) 3 times a day for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralam Hospital and Shariati Hospital

Full name of responsible person

Dr. Alireza Khajehnasiri

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Tehran Medical Sciences

Full name of responsible person

Dr.Gholamreza Amin

Street address

Tehran University Of Medical Sciences, 16 Azar Street

City

Tehran

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

Yes

Title of funding source

Vice Chancellor for Research of Tehran 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

Dr.Alireza Khajehnasiri

Position

Pain Fellowship/Assistant Professor of Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Pharmacy Student

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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