

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of dried hydro alcoholic extract of pomegranate pericarp on oxidattive and inflammation state, Metaloproteinase 1, metabolic markers and clinical sign in women with knee osteoarthritis

Protocol summary

Summary

This randomized double blind clinical trial was aimed to assess effects of dried hydro alcoholic extract of pomegranate pericarp on oxidattive and inflammation state, Metaloproteinase 1, metabolic markers and clinical sign in women with knee osteoarthritis disease severity from mild to moderate. Eighty 38-60 aged knee osteoarthritis patients within the Body Mass Index range of 30-35 kg/m2 will divide in to two control and intervention group. Intervention group will receive2* 500 mg dried hydro alcoholic extract of pomegranate pericarp while the control group will recive2 *500 mg placebo daily. Both of groups will receive standard drug therapy (2 tab acetaminophen 500,1 tab glocosamine) during two months of study. 3 day diet record, physical activity questionnaire will fill at beginning, middle and the end of study. Blood sampling, assessment of anthropometric measurements and biochemical indices (Oxidative and Inflammatory state, Metaloproteinase 1 and Lipid profile) will take at the beginning and the end of study. All subjects will instruct to maintain their usual diet and physical activity throughout the study and not to consume any extra NSAIDs or analgesics .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405183664N11**
Registration date: **2014-10-27, 1393/08/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-10-27, 1393/08/05

Registrant information

Name

Maryam Rafrat

Name of organization / entity

Tabriz University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2014-12-06, 1393/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dried hydro alcoholic extract of pomegranate pericarp on oxidattive and inflammation state, Metaloproteinase 1, metabolic markers and clinical sign in women with knee osteoarthritis

Public title

Effect of dried hydro alcoholic extract of pomegranate pericarp on oxidattive and inflammation state, Metaloproteinase 1, metabolic markers and clinical sign in women with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: females aged 38-60 years-old! Primary bilateral knee osteoarthritis with mild to moderate severity based on American College of Rheumatology criteria! Body mass index within range of 30-35 kg/m² ! Exclusion criteria : Severe osteoarthritis(grade IV)! Secondary knee osteoarthritis based on ACR criteria! knee surgery or intra-articular injection! Neuromuscular diseases ! diabetes! cardiovascular disease! metabolic diseases! kidney and hepatic diseases! Smoking! Alcohol intake! Vitamin and Mineral,W3, W6 and other antioxidant supplement consumption one month before study and throughout the study! History of MI! History of peptic or duodenal ulcers! Allergy to pomegranate! Use of non-steroidal anti-inflammatory drugs(one week before study until the end of study)30 :<BMI & BMI>35kg/m² !

Age

From **38 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

no where

Secondary trial Id

0000

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah st.

City

Tabriz

Postal code

Approval date

2014-05-11, 1393/02/21

Ethics committee reference number

9328

Health conditions studied

1

Description of health condition studied

osteoarthritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

MDA

Timepoint

befor and the end of study

Method of measurement

mmol/l

2

Description

TAC

Timepoint

befor and the end of study

Method of measurement

mmol/l

3

Description

GPX,SOD

Timepoint

befor and the end of study

Method of measurement

unit/hemogloboline g

4

Description

MCP1, NFkB

Timepoint

befor and the end of study

Method of measurement

pg/ml

5

Description

hs-CRP

Timepoint

befor and the end of study

Method of measurement

mg/l

6**Description**

MMP1

Timepoint

befor and the end of study

Method of measurement

pg/ml

7**Description**

lipid profile

Timepoint

befor and the end of study

Method of measurement

mg/dl

8**Description**

sistolic and diastolic BP

Timepoint

befor and the end of study

Method of measurement

mmHg

Secondary outcomes**1****Description**

physical activity

Timepoint

befor,middle and the end of study

Method of measurement

qustionarie

2**Description**

BMI

Timepoint

befor and the end of study

Method of measurement

kg/m2

3**Description**

weight

Timepoint

befor and the end of study

Method of measurement

kg

4**Description**

macro and micro nutrients

Timepoint

befor,middler and the end of study

Method of measurement

questionarie

Intervention groups**1****Description**

intervention group: 500mg dried hydro alcoholic extract of pomegranate pericarp capsule twice a day

Category

Treatment - Drugs

2**Description**

control group:500 mg placebo capsule (starch)

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Dr Bina Eftekhari Sadat

Street address

Daneshgah st,next to faculty of dentistry

City

Tabriz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Dr MR Rashidi

Street address

research vice chancellor of Tabriz University of Medical Sciences, Daneshgah St, Tabriz

City

Tabriz

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 Tabriz 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

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Person responsible for general inquiries

Contact

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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