

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effect of Arctium lappa root (Burdock) tea consumption on serum levels of oxidative stress markers, inflammatory markers, lipid profile and clinical symptoms in patient with knee osteoarthritis

Protocol summary

Summary

The purpose of this study was to investigate the effects of Arctium lappa root (Burdock) tea consumption on serum levels of oxidative stress markers, inflammatory markers, lipid profile, clinical symptoms and nutritional status in patient with knee osteoarthritis. Inclusion criteria: age 50-70years old; primary bilateral knee osteoarthritis based on ACR criteria; ability to consume arctium lappa tea. Exclusion criteria: grade IV osteoarthritis; secondary OA; active synovitis; knee surgery or intra-articular injection; neuromuscular diseases; diabetes; metabolic diseases; cardiovascular diseases; hepatic diseases; smoking; alcohol and MI. A total of 42 patients(both of gender) grade 1-3 osteoarthritis, aged 50 to 70 years old, were randomly assigned into intervention or control group. The patients in both groups received physiotherapy (20 an-hour sessions for both knees) as well as Acetaminophen 500 mg twice a day and Glucosamine one tablet daily for 6 weeks. The patients in the intervention group received, as well, 6 grams of Arctium lappa root (Burdock) tea daily for 6 weeks. The inflammatory markers including IL-6 and hs-CRP as well as lipid profile, clinical signs, anti-oxidative status, anthropometric and dietary intake assessments were measured before and after the intervention and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305274105N13**

Registration date: **2013-06-29, 1392/04/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-06-29, 1392/04/08

Registrant information

Name

Beit Allah Alipour

Name of organization / entity

Health & Nutrition Faculty

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

alipourb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Arctium lappa root (Burdock) tea consumption on serum levels of oxidative stress markers, inflammatory markers, lipid profile and clinical symptoms in patient with knee osteoarthritis

Public title

Effect of Arctium lappa root (Burdock) tea consumption

on serum levels of oxidative stress markers, inflammatory markers, lipid profile and clinical symptoms in patient with knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 50-70years old; primary bilateral knee osteoarthritis based on ACR criteria; ability to consume arctium lappa tea . Exclusion criteria: grade IV osteoarthritis; secondary OA; active synovitis; knee surgery or intra-articular injection; neuromuscular diseases; diabetes; metabolic diseases; cardiovascular diseases; hepatic diseases; smoking; alcohol and MI.

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **42**

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

Ethic committee of Tabriz University of Medical Sciences

Street address

Attare Neyshaburi St, Tabriz, East Azarbijan, Iran

City

Tabriz

Postal code

Approval date

2013-04-29, 1392/02/09

Ethics committee reference number

9231

Health conditions studied

1

Description of health condition studied

knee OA

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Pain, joint stiffness and Disability

Timepoint

Before and 6 weeks after the intervention

Method of measurement

Knee injury Osteoarthritis Outcome Score (KOOS) questionnaire

2

Description

Timed up and go test

Timepoint

Before and 6 weeks after the intervention

Method of measurement

based on walking time

3

Description

Visual Analog Scale (VAS)

Timepoint

Before and 6 weeks after the intervention

Method of measurement

based on line

4

Description

Inflammatory markers (IL-6)

Timepoint

Before and 6 weeks after the intervention

Method of measurement

Elisa

5

Description

hs-crp

Timepoint

Before and 6 weeks after the intervention

Method of measurement

Imonoturbidometry

6

Description

Markers of Lipidemia

Timepoint

Before and 6 weeks after the intervention

Method of measurement

Espectrophotometry(mg/dl)

7**Description**

measurement of serum MDA

Timepoint

Before and 6 weeks after the intervention

Method of measurement

spectrophotometry

8**Description**

Erythrocyte SOD activity

Timepoint

Before and 6 weeks after the intervention

Method of measurement

spectrophotometry

9**Description**

Erythrocyte GPX activity

Timepoint

Before and 6 weeks after the intervention

Method of measurement

spectrophotometry

10**Description**

Serum total antioxidant capacity

Timepoint

Before and 6 weeks after the intervention

Method of measurement

spectrophotometry

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

physical activity

Timepoint

Before and 6 weeks after the intervention

Method of measurement

physical activity Questionnaire

2**Description**

Macronutrients intake

Timepoint

Before and 6 weeks after the intervention

Method of measurement

24-h recall Questionnaire

3**Description**

Anthropometric index(weight and Body Mass Index)

Timepoint

Before and 6 weeks after the intervention

Method of measurement

Analogue scale for weight and weight(Kg)/Square Height for body mass index

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

Arctium lappa root (Burdock) tea daily, for 6 weeks as well as physiotherapy (20 an-hour sessions for both knees), Acetaminophen 500mg twice a day, and Glucosamine one tablet daily for 6 weeks

Category

Treatment - Other

2**Description**

control: Physiotherapy (20 an-hour sessions for both knees) as well as Acetaminophen 500mg twice a day and Glucosamine one tablet daily for 6 weeks

Category

Treatment - Drugs

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

Shohadaa hospital, Tabriz university of medical science

Full name of responsible person

Dr Eftekhar Sadat

Street address

Golshahr St.Tabriz, East Azarbijan

City

Tabriz

2**Recruitment center****Name of recruitment center**

Shahid Madani hospital, Tabriz university of medical science

Full name of responsible person

Dr Eftekhar Sadat

Street address

Daneshgah st.Tabriz, East Azarbijan

City

Tabriz

3**Recruitment center****Name of recruitment center**

Faculty of Rehabilitation, Tabriz university of medical science

Full name of responsible person

Dr. Mir Ali Eteraf Oskouei, PhD, PT Dr. Mir Ali Eteraf Oskouei, PhD, PT

Street address

Faculty of Rehabilitation, Tavanir St., ValiAsr Ave, Tabriz, East Azarbayjan

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Seyed Kazem Shakouri

Street address

Golbad Street, Tabriz, East Azarbayjan

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, 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

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Leila Maghsumi Noroozabad

Position

MSc student in nutrition sciences

Other areas of specialty/work

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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