

# 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**

**Street address**

Health and Nutrition faculty, Attare Neishabouri Avenue, Golgasht street

**City**

Tabriz

**Postal code**

**Phone**

00

**Fax**

**Email**

l.maghsumi55@gmail.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Leila Maghsumi Noroozabad

**Position**

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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*