Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Sesame Seed on inflammatory markers and clinical sign in patient with knee osteoarthritis

Protocol summary

Summary

The purpose of this study was to investigate the effects of sesame on lowering serum lipids and enhancing antioxidant capacity and improving clinical signs in people with knee osteoarthritis. A total of 50 patients 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 1-hour sessions for both knees) as well as Acetaminophen 500mg twice a day and Glucosamine one tablet daily for two months. The patients in the intervention group received, as well, 40 grams of sesame powder daily for 2 months. The inflammatory markers including IL-6and hs-CRP as well as lipid profile, clinical signs and anti-oxidative status were measured before and after the intervention and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011164105N4**
Registration date: **2011-01-15, 1389/10/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-01-15, 1389/10/25

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

faculty of health and nutrition-tabriz

Expected recruitment start date

2010-11-01, 1389/08/10

Expected recruitment end date

2010-11-20, 1389/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Sesame Seed on inflammatory markers and clinical sign in patient with knee osteoarthritis

Public title

Effect of Sesame Seed on inflammatory markers and clinical sign in patient with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 50-70years old, primary bilateral knee osteoarthritis based on ACR criteria, ability to consume and sesame 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, vitamin, and mineral supplement consumption, MI

Age

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

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences and Health Services
Street address
Attare Neyshaburi St, Tabriz
City
Tabriz
Postal code
Approval date
2010-11-08, 1389/08/17
Ethics committee reference number
8941

Health conditions studied

1

Description of health condition studied
knee OA
ICD-10 code
M17.0
ICD-10 code description
Primary gonarthrosis, bilateral

Primary outcomes

1

Description
Inflammatory markers (IL-6)
Timepoint
Before and after the intervention
Method of measurement
Elisa

2

Description
Markers of Lipidemia
Timepoint
Before and after the intervention
Method of measurement
Espectrophotometry(mg/dl)

3

Description
clinical sign
Timepoint
Before and after the intervention
Method of measurement
physical assessment

4

Description
Timed up and go test
Timepoint
Before and after the intervention
Method of measurement
based on walking time

5

Description
hs-CRP
Timepoint
Before and after the intervention
Method of measurement
Imonoturbidometry

6

Description
Koos questionnaire
Timepoint
before and after intervention
Method of measurement
Koos questionnaire

Secondary outcomes

1

Description
GPX
Timepoint
Before and after the intervention
Method of measurement
u/gr Hemoglubin- spectrophotometry

2

Description
SOD
Timepoint

Before and after the intervention

Method of measurement

spectrophotometry

3

Description

MDA

Timepoint

Before and after the intervention

Method of measurement

spectrophotometry

4

Description

Total Antioxidant

Timepoint

Before and after the intervention

Method of measurement

spectrophotometry

Intervention groups

1

Description

Sesame powder, 40 grams daily, for 2 months as well as physiotherapy (20 an-hour sessions for both knees), Acetaminophen 500mg twice a day, and Glucosamine one tablet daily for two months

Category

Treatment - Other

2

Description

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

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaa hospital

Full name of responsible person

Dr Eftekhar Sadat

Street address

Golshahr St.

City

Tabriz

2

Recruitment center

Name of recruitment center

Shahid Madani hospital

Full name of responsible person

Dr Eftekhar Sadat

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

Full name of responsible person

Dr Rasool Azarfarin

Street address

Daneshgah St.

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences and Health Services

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

Beit Allah Alipour

Position

Assistant Professor

Other areas of specialty/work

Street address

Faculty of Health and Nutrition,Attare Neyshaburi St.

City

Tabriz

Postal code

Phone

+98 41 1335 7580

Fax
Email
balipoor@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sceinces
Full name of responsible person
Beit Allah Alipour
Position
Other areas of specialty/work
Street address
Faculty of Health and Nutrition
City
Tabriz
Postal code
Phone
+98 41 1335 7580
Fax
Email
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