

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Evaluation of the effect oral food product Prepared from chicken feet On anthropometric indicators , Lipid profile, pain reduction, inflammation reduction , And Improving the quality of life On patients with Knee osteoarthritis

Protocol summary

Study aim

Determination of the oral effect of chicken feet on anthropometric indices, lipid profile, pain relief, inflammation reduction and quality of life improvement in patients with knee osteoarthritis

Design

Randomized clinical trial, simple randomization on 50 patients and how to randomize using computer-generated numbers

Settings and conduct

This clinical trial study was performed on 50 patients (25 patients in each group) referred to Motahhari Hospital with osteoarthritis of the knee. At the beginning and end of the study, anthropometric information including height, weight and body mass index and three Food Remembrance Day (two days early in the week and one day in the weekend) is taken from individuals and then the Western Ontario McMaster Universities (WOMAC) and Visual Analogue Scale (VAS) questionnaires are used to assess patients before and after the intervention. Blood samples are also taken before and after 56 days to check for inflammation and blood lipid levels.

Participants/Inclusion and exclusion criteria

People with grade 2 to 4 osteoarthritis who do not have a history of chronic illness, including diabetes, liver disease, psychiatric disorders and other knee-related illnesses, are included in the study.

Intervention groups

Our intervention is burgers made from chicken feet

Main outcome variables

Reduce inflammation, improve quality of life, reduce pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140127016375N2**

Registration date: **2020-10-10, 1399/07/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-10, 1399/07/19**

Update count: **0**

Registration date

2020-10-10, 1399/07/19

Registrant information

Name

Siavash Babajafari

Name of organization / entity

School of Nutrition and food sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 7288

Email address

jafaris@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-15, 1398/12/25

Expected recruitment end date

2020-11-15, 1399/08/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect oral food product Prepared from chicken feet On anthropometric indicators , Lipid profile, pain reduction, inflammation reduction , And Improving the quality of life On patients with Knee osteoarthritis

Public title

Evaluation of the effect oral food product Prepared from chicken feet On anthropometric indicators , Lipid profile, pain reduction, inflammation reduction , And Improving the quality of life On patients with Knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Men and women in the age group between 30 to 65 years Non-traumatic knee pain for more than 3 months Osteoarthritis Limit 2 to 4 Based on the article Introduction - Lawrence Kelgren Daryiography, which has been re-funded in the last 6 months No history of chronic diseases including diabetes, liver disease, psychiatric disorders no pregnancy and lactation Lack of septic arthritis, inflammatory joint disease, gout No intra-articular injection in either knee during the last 3 months (6 months for hyaluronic acid) Do not take NSAIDs or alternative therapies for osteoarthritis in the last 15 days and treatment with chondroitin sulfate and glucosamine in the last 3 months

Exclusion criteria:

Failure to follow the study means not consuming more than 80% of the intervention Acute illness or hospitalization

Age

From **30 years** old to **65 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

Simple randomization: In this method, the computer generates numbers between 0 and 1, and if the number is less than 0.5, it is in the intervention group and more than 0.5 in the control group.

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

ZAND BOUIEVARD

City

SHIRAZ

Province

Fars

Postal code

71348-14336

Approval date

2020-03-15, 1398/12/25

Ethics committee reference number

IR.SUMS.REC.1398.1386

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

Primary outcomes

1

Description

Improving quality of life in womac questionnaire

Timepoint

At the beginning of the study and the 30th day of the study and the last day of the study

Method of measurement

Womac questionnaire

Secondary outcomes

1

Description

Reduction of inflammation in patients

Timepoint

At the beginning and end of the study

Method of measurement

blood sample

Intervention groups

1

Description

Intervention group: 25 people who have the conditions to

study, after randomization, enter the intervention group and are given chicken leg burgers, which should consume a 100-gram burger per day, and also taught them selected exercises to improve knee movements. Necessary examinations will be performed after 8 weeks

Category

Treatment - Other

2

Description

Control group: 25 people who have the conditions to study after randomization enter the control group and they are not given chicken feet burgers and only they are taught selected exercises to improve knee movements. After 8 weeks, the necessary examinations are performed

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

MOTAHHARI HOSPITAL, SHIRAZ

Full name of responsible person

SIYAVASH BABA JAFARI

Street address

ZAND BOULEVARD

City

SHIRAZ

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 5410

Email

moslemaskarpour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

YOUNES GHASEMI

Street address

ZAND BOULEVARD

City

SHIRAZ

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 5410

Email

info@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

MOSLEM ASKARPOOR

Position

STUDENT

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

VALIASR

City

FADAMI

Province

Fars

Postal code

7488134445

Phone

+98 71 5369 2173

Email

moslemaskarpour@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

moslemaskarpour

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

valiasr

City
fadami
Province
Fars
Postal code
7488134445
Phone
+98 71 5369 2173
Email
moslemaskarpoor@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
moslem askarpoor
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
valiasr
City
fadami
Province
Fars
Postal code
7488134445
Phone
+98 71 5369 2173
Email
moslemaskarpoor@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All personal information of the participants can be shared after identifying them

When the data will become available and for how long

Access starts from 1399 to one year after the results are published

To whom data/document is available

All academics and industry workers

Under which criteria data/document could be used

The right to use is only for themselves and not for others and they are required to include the name of the servant as a colleague

From where data/document is obtainable

Muslim Askarpour by email
moslemaskarpoor@uahoo.com

What processes are involved for a request to access data/document

The applicant submits his / her request to the mentioned emails and we provide the information to them

Comments