Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The efficacy of chickpeas diet on clinical symptoms of patients with osteoarthritis of the knee

Protocol summary

Study aim
Determination of the efficacy of oral chickpeas on the clinical symptoms of patients with knee osteoarthritis

Design
Non randomized non controlled clinical trial, phase 2. The sample size is 45 patients. The enrolled patients will follow up for one month.

Settings and conduct
This study is done in Imam Khomeini Hospital of Falavarjan, and the type of this study is before-after. Blinding does not occur in this study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 1. Positive history of rheumatoid arthritis disease; 2. Positive history of goat disease; 3. Positive history of Calcium Pyrophosphate Deposition Disease 4. Being afflicted with uncontrolled cardiovascular disease; 5. Being afflicted with proven malignancies Creatinine level is greater than 3 mg /dl 6. Receiving oral corticosteroids during 4 weeks ago 7. Receiving nonsteroidal anti-inflammatory (NSAIDs) drugs at the doses greater than 50 mg daily (except aspirin); 8. Receiving acetaminophen at the doses greater than 650 mg daily; 9. Receiving intra-articular medications during three months ago; 10. Unwillingness or inability of the patient to answer the questions of the questionnaire used in the study. Exclusion criteria: 1.Patients in the rage of 40 to 80 years old 2.The (American College of Rheumatology) ACR clinical criteria for knee osteoarthritis were fulfilled 3.Patients with knee osteoarthritis in grades of 1, 2, and 3

Intervention groups
Intervention group: Patients with knee osteoarthritis receiving chickpeas with the dosage of a cup of chickpeas for lunch and dinner meals in the days of 1 to 5 of treatment period, then continue to eat chickpeas for two meals per week until fourth week of treatment

Main outcome variables
Pain, activities of daily living, sport and recreation function, and knee-related quality of life in patients with knee osteoarthritis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150825023753N12**
Registration date: **2019-07-20, 1398/04/29**
Registration timing: **retrospective**

Last update: **2019-07-20, 1398/04/29**
Update count: **0**

Registration date
2019-07-20, 1398/04/29

Registrant information

Name
Mohammad Mahdi Parvizi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3212 5592

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-09, 1396/01/20

Expected recruitment end date
2018-06-20, 1397/03/30

Actual recruitment start date
2017-04-21, 1396/02/01

Actual recruitment end date
2019-01-20, 1397/10/30

Trial completion date

2019-02-19, 1397/11/30

Scientific title
The efficacy of chickpeas diet on clinical symptoms of patients with osteoarthritis of the knee

Public title
The efficacy of chickpeas diet on clinical symptoms of osteoarthritis of the knee

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients in the rage of 40 to 80 years old The American College of Rheumatology (ACR) clinical criteria for knee osteoarthritis were fulfilled Patients with osteoarthritis of the knee grades 1, 2, and 3

Exclusion criteria:
Positive history of rheumatoid arthritis disease Positive history of goat disease Positive history of Calcium Pyrophosphate Deposition Disease Being afflicted with uncontrolled cardiovascular disease Being afflicted with proven malignancies Creatinine level is greater than 3 mg /dl Receiving oral corticosteroids during 4 weeks ago Receiving nonsteroidal anti-inflammatory (NSAIDs) drugs at the doses greater than 50 mg daily (except the aspirin) Receiving acetaminophen at the dosage of greater than 650 mg daily Receiving intra-articular medications during three months ago Unwillingness or inability of the patient to answer the questions of the questionnaire used in the study

Age
From **40 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **45**
Actual sample size reached: **45**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee on Biomedical Research of Shahid Beheshti University of Medical sciences

Street address
Shahid Beheshti University of Medical sciences, Daneshju Blv

City
Tehran

Province
Tehran

Postal code
1983963113

Approval date
2017-01-09, 1395/10/20

Ethics committee reference number
IR.SBMU.RETECH.REC.1395.628

Health conditions studied

1

Description of health condition studied
Osteoarthritis of knee

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
knee pain

Timepoint
One month

Method of measurement
Questionnaire of knee Injury and Osteoarthritis Outcome Score (KOOS questionnaire)

2

Description
Knee function

Timepoint
One month

Method of measurement
Questionnaire of knee Injury and Osteoarthritis Outcome Score (KOOS questionnaire)

3

Description
Sport and Recreation Function

Timepoint
One month

Method of measurement
Questionnaire of knee Injury and Osteoarthritis Outcome Score (KOOS questionnaire)

4

Description
Activities of daily living,
Timepoint
One month
Method of measurement
Questionnaire of knee Injury and Osteoarthritis Outcome Score (KOOS questionnaire)

5

Description
Knee-related quality of life
Timepoint
One month
Method of measurement
Questionnaire of knee Injury and Osteoarthritis Outcome Score (KOOS questionnaire)

Secondary outcomes

1

Description
Patient satisfaction from treatment
Timepoint
One month
Method of measurement
Global patient assessment questionnaire

Intervention groups

1

Description
Intervention group: Administrating a cup of chickpeas for lunch and dinner meals in the first five days of treatment, and then continuing to eat chickpeas for two meals per week to fourth week of treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Falavarjan
Full name of responsible person
Dr Roshanak Mokaberinejad
Street address
Isfahan Province, Falavarjan, Kamarbandi Jonobi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Neda Ahmadi
Position
PhD student of traditional Persian medicine
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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
Demographic data and the result of the clinical trial
When the data will become available and for how long
6 month later
To whom data/document is available
Researchers
Under which criteria data/document could be used
After publication of the extracted article of the clinical trial
From where data/document is obtainable
Sending Email to the researchers
What processes are involved for a request to access data/document
Sending the request via the email
Comments