Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Study of the effect of resistance training and nano curcumin supplementation on synovial fluid biomarkers in patients with knee osteoarthritis.

Protocol summary

Study aim

study of the effect of resistance training and nano-curcumin use on synovial fluid biomarkers in patients with knee osteoarthritis.

Design

Because of the importance of group homogeneity, the stratified randomization method is used In which the removal of possible heterogeneity is done by classifying the variables of the disease grade prior to random assignment. Double Blind Clinical Trial,calculate the sample size based on the formula and by conducting pilot studies.

Settings and conduct

Initial measurements and pre-test at the Center for Physiotherapy at the site of the protocol implementation,performing resistance training 3 days a week for 2 months. Nanocurcumin supplement daily 1 and placebo daily1(soft gelatin capsule with a completely similar appearance of nano-curcumin) will be provided randomly, without the knowledge of participants, clinical care, evaluator and analyst.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Infection with osteoarthritis grade1-4,Low activity,age 60-45, non-acute illness , fracture , ,joint infections, Exclusion criteria: Unwillingness of patients to continue cooperation , lack of synovial fluid, Knee joint movement restriction, Injury when exercising , drug use other than diclofenac for the treatment of Osteoarthritis , Cardiovascular, liver, diabetes, kidney failure,age less than 45 and over 60,addiction and alcohol and smoking.

Intervention groups

Patients with knee Osteoarthritis who:1- perform resistance training with nano-Curcumin supplementation2- perform resistance training with placebo 3- take nano-curcumin supplement4- only take placebo(control group)

Main outcome variables

Levels of synovial fluid biomarkers in patients with knee osteoarthritis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161208031300N1**
Registration date: **2018-05-11, 1397/02/21**
Registration timing: **retrospective**

Last update: **2018-05-11, 1397/02/21**
Update count: **0**

Registration date

2018-05-11, 1397/02/21

Registrant information

Name

Reza Ganji

Name of organization / entity

North Khorasan University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-11, 1396/09/20

Expected recruitment end date

2018-02-09, 1396/11/20

Actual recruitment start date

2017-12-11, 1396/09/20

Actual recruitment end date

2018-02-20, 1396/12/01

Trial completion date

empty

Scientific title

Study of the effect of resistance training and nano curcumin supplementation on synovial fluid biomarkers in patients with knee osteoarthritis.

Public title

The effect of resistance training and nano curcumin supplementation on synovial fluid biomarkers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having an OA (primary) knee with a grade of 1 to 4 Low mobility (Participate in sports activities less than three times a week for less than 20 minutes during the past six months and lack of participation in organized activities over the past year) The age range is between 45-60 years Non-acute illness like cardiovascular disease and lack of fracture and injury In the lower extremity or a joint infection Lack of endocrine and metabolic diseases (diabetes, thyroid, kidney, liver), cardiovascular disease (high blood pressure, coronary artery disease and atherosclerosis, peripheral vascular diseases and myocardial infarction), mental illness (depression, Schizophrenia and mania), epilepsy, anemia, cancer and any infectious disease. No history of alcohol and smoking and any addiction

Exclusion criteria:

Unwillingness of patients to continue cooperation in research No synovial fluid during aspiration Knee joint limitation and inability to perform sports exercises Any injuries when doing exercises Taking medications other than diclofenac for the treatment of osteoarthritis Suffering from cardiovascular, liver, diabetes, kidney failure Age range less than 45 and more than 60 years Addiction and alcohol and smoking Joint infection

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done with random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The medication and placebo are coded by the investigator and distributed randomly among the patients.Researchers, clinical caregivers, evaluators, and analysts do not know what type of supplement they are using.

Placebo

Used

Assignment

Factorial

Other design features

According to our knowledge, to date, there have been very limited studies in the field of resistance training with the use of nanocurcumin supplementation in patients with knee osteoarthritis.Investigating changes in the level of inflammatory and cartilage factors in synovial fluid , we will show a more accurate comparison of the effects of resistance training and the effect of supplementation of nano-corcomin alone and simultaneously.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Bojnourd University of Medical Sciences

Street address

Shahid Mohagher Alley,Shahid Beheshti St, Research and Technology Dept. of North Khorasan University of Medical Sciences

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Approval date

2018-03-13, 1396/12/22

Ethics committee reference number

ir.nkums.rec.1396.77

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

Primary outcomes

1

Description
Levels of synovial fluid biomarkers of the knee
Timepoint
24 hours before the intervention and 48 hours after the end of the intervention
Method of measurement
Enzyme-Linked Immunosorbent Assay test

Secondary outcomes

1

Description
Knee pain
Timepoint
24 hours before the intervention and 24 hours after the intervention
Method of measurement
Western Ontario and McMaster Universities Osteoarthritis Index,Visual Analogue Scale

2

Description
improving the quality of life
Timepoint
24 hours before the intervention and 24 hours after the intervention
Method of measurement
Health Assessment Questionnaire

Intervention groups

1

Description
Intervention group:Patients with Knee Osteoarthritis who use nano-curcumin supplementation with resistance training.Exercise groups for 2 months, 3 days a week, knee and hip exercises, including knee extension, pelvic abduction, pelvic edema and plantar flexion, and quadrice chairs, then with a intensity of 50-75% 1RM, will last until the endurance.nano-curcumin supplement of the company Sinacurcumin with a dose of 1000 mg (equivalent to 80 mg of nanosilver), and daily 1, and placebo daily 1(soft gelatin capsule).
Category
Treatment - Drugs

2

Description
Second intervention group : Patients with Knee Osteoarthritis who take a placebo with their resistance training .The training groups will perform for 2 months, 3 days a week, knee and hip exercises, including knee extension, pelvic abduction, pelvic edema and plantar flexion, and quadrice chairs, then with a intensity of 50-75% 1RM until the pressure is tolerated. Placebo
Category
Rehabilitation

3

Description
Third intervention group:Patients with Knee Osteoarthritis that use supplement nano-curcumin.Nanocorcinol supplements are produced by the company Sinacurcumin at a dose of 1000 mg (equivalent to 80 mg Nanosciences) and daily 1 tablet.
Category
Treatment - Drugs

4

Description
Control group: Patients with Knee Osteoarthritis who use one placebo per day.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Specialized Clinic
Full name of responsible person
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Sponsors / Funding sources

1

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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
Bojnourd University of Medical Sciences

Proportion provided by this source
60

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

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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

Information about the main outcome of this study will be shared through the article.

When the data will become available and for how long

The start of the access period will be 3 month after the results are printed.

To whom data/document is available

Researchers working in academia and academics and industry professionals

Under which criteria data/document could be used

Terms of use of data or documentation:1. Having specialized knowledge and academic competence in the research subject 2. Present actual research results 3. Failure to remove or modify the original address of the authors of scientific articles 4. Observe the interests of stakeholders at all stages 5. No publication of the results of the plan without coordination and obtaining a license

From where data/document is obtainable

1- Dr. Reza Ganji: r.ganji@nkums.ac.ir 2. Dr. Sadegh Cheragh Birjand: s_birjandi2001@yahoo.com

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

Applicants for documentation and data files can apply to the announced email addresses by sending a valid academic and academic application.After verifying the documents submitted, the documents and data files will be provided to the applicants.

Comments