# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 Jun 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

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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

**City**

Bojnurd

**Province**

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**Postal code**

94176914735

**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**
Reza Ganji
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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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**