Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Examining the topical effectiveness of Joint‘s cream (A production of Iranian Traditional Medicine - ITM) on pain and function in patients with Osteoarthritis of the knee.

Protocol summary

Study aim

Investigating the topical effect of Joint cream (A production of Traditional Iranian Medicine) on the Outcome of Pain and Function in Patients with Knee Osteoarthritis

Design

The first group runs the usual program for the treatment of osteoarthritis (including patient education, exercise, weight loss, Using insoles, physiotherapy, and medication use). The second group, in addition to the usual program of treatment for osteoarthritis (described above), also uses topical arthritis cream (Persian medicine product). The study is a clinical trial with a controlled and randomized control group. Meanwhile, the study is not blind and is done in Phase 3. The sample size is defined as 40 pathent (20 pathent per group).

Settings and conduct

Individuals after obtaining consent to participate in this study are divided into two groups of 20 A and B by stratified balanced block randomization.Then, in both groups, two questionnaires including visual analog scale and KOOS were used to assess pain and function before and after the intervention. Also, 6MWT, Timed up and go test and 30 second chair stand tests were evaluated for performance evaluation in these patients. The patient in A group runs the usual program for the treatment of osteoarthritis (including patient education, exercise, weight loss, Using insoles, physiotherapy, and medication use).The patient in B group, in addition to the usual program of treatment for osteoarthritis (described above), also uses topical arthritis cream (Persian medicine product).The method of using the product (daily at two times in the morning and night) is merely rubbing the cream on the knee joint without massage. Both groups were reassessed 2 times, 4 and 8 weeks after the onset of the course, and both groups completed again the visual analog score and KOOs questionnaires. Both groups A and B are evaluated based on the comparison of two questionnaires before and after the intervention in terms of pain relief and increased performance. This study was carried out in Sport Medicine Clinic of Tehran University of Medical Sciences in Imam Khomeini Hospital.

Participants/Inclusion and exclusion criteria

Entry requirements: Age over 40 years Having diagnostic criteria for knee osteoarthritis (defined by the American College of Rheumatology) Having grade 2 or 3 osteoarthritis according to radiological criteria Having a BMI of 20-35 Non-arrival conditions: History of rheumatoid arthritis History of knee or hip replacement surgery in the affected joint History of any lower limb surgery over the past 6 months History of intra-articular corticosteroid injection in the last 6 months History of intra-articular injection of gel and PRP in the last year The onset of opioid analgesics or oral corticosteroids over the past four weeks

Intervention groups

The first group runs the usual program for the treatment of osteoarthritis (including patient education, exercise, weight loss, Using insoles, physiotherapy, and medication use). The second group, in addition to the usual program of treatment for osteoarthritis (described above), also uses topical arthritis cream (Persian medicine product).

Main outcome variables

The Effect of Local use of Joints cream (Persian medicine product) on pain and function in patients with knee osteoarthritis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150613022689N6**
Registration date: **2018-03-19, 1396/12/28**

Registration timing: **prospective**

Last update: **2018-03-19, 1396/12/28**
Update count: **0**

Registration date
2018-03-19, 1396/12/28

Registrant information

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Name of organization / entity
School of Traditional Medicine Tehran University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2018-09-23, 1397/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Examining the topical effectiveness of Joint‘s cream (A production of Iranian Traditional Medicine - ITM) on pain and function in patients with Osteoarthritis of the knee.

Public title
Examining the topical effectiveness of Joint‘s cream on patients with Osteoarthritis of the knee.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 40 years Having diagnostic criteria for knee osteoarthritis (defined by the American College of Rheumatology) Having grade 2 or 3 osteoarthritis according to radiological criteria Having a BMI of 20-35

Exclusion criteria:
History of rheumatoid arthritis History of knee or hip replacement surgery in the affected joint History of any lower limb surgery over the past 6 months History of intra-articular corticosteroid injection in the last 6 months History of intra-articular injection of gel and PRP in the last year The onset of opioid analgesics or oral corticosteroids over the past four weeks

Age
From **40 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals after obtaining consent to participate in this research are divided by method stratified balanced block randomization; Into two groups (A and B) with 20 people in every group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
The ethics committee of Tehran university of medical sciences

Street address
Sixth floor, , central building of the Tehran university of medical sciences , Ghods street , Keshavarz blvd

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2017-05-21, 1396/02/31

Ethics committee reference number
IR.TUMS.VCR.REC.1396.2336

Health conditions studied

1

Description of health condition studied
Osteoarthritis of the knee

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain
Timepoint
At the beginning of the study (before intervention), 4 and 8 weeks after the use of joint cream.
Method of measurement
Using visual analog scale and KOOS questionnaires

2

Description
Function
Timepoint
At the beginning of the study (before intervention), 4 and 8 weeks after the use of joint cream.
Method of measurement
Using visual analog scale and KOOS questionnaires

Secondary outcomes

1

Description
Localized swelling
Timepoint
At the beginning of the study (before intervention), 4 and 8 weeks after the use of joint cream.
Method of measurement
Using visual analog scale and KOOS questionnaires and 6MWT, Timed up and go test tests and 30 second chair stand test.

2

Description
Range of knee joint movements
Timepoint
At the beginning of the study (before intervention), 4 and 8 weeks after the use of joint cream.
Method of measurement
Using visual analog scale and KOOS questionnaires and 6MWT, Timed up and go test tests and 30 second chair stand test.

3

Description
Life satisfaction
Timepoint
At the beginning of the study (before intervention), 4 and 8 weeks after the use of joint cream.
Method of measurement
Using visual analog scale and KOOS questionnaires and 6MWT, Timed up and go test tests and 30 second chair stand test.

Intervention groups

1

Description
Control group: Patients in the control group perform the usual program of treatment for osteoarthritis (including patient education, exercise, weight loss, use insoles, physiotherapy, and medication use).
Category
Treatment - Other

2

Description
Intervention group: Patients in the intervention group also use topical arthritis cream (Persian medicine product) in addition to the usual program for the treatment of osteoarthritis (including patient education, exercise, weight loss, use insoles, physiotherapy and the use of medications).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sports medicine clinic of Imam Khomeini hospital
Full name of responsible person
Tohid Seif Barghi
Street address
Imam Khomeini hospital complex ,the end of Keshavarz blvd
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tohid_seif@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
dr.Sahraeian
Street address
At the beginning of Ghods Street, Keshavarz Blvd;Tehran
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ekhadem@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Ebrahim Khadem Azghadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional 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
Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable patients.

When the data will become available and for how long

Starting the access period is 6 months after printing the results.

To whom data/document is available

Researchers working in academic and academic institutions as well as those involved in related industries.

Under which criteria data/document could be used

For use in similar scientific studies as well as related pharmaceutical industries.

From where data/document is obtainable

Dr e.khadem Contact number: 09123054043 E-mail address: ekhadem@tums.ac.ir

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

In agreement with the contact number or e-mail address mentioned, the announcement of the data or documentation used will be made available to the applicant.

Comments