Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the therapeutic effect of topical Wishca,Diclofenac and Capsaicin in patient with knee Osteoarthritis

Protocol summary

Study aim
Comparing the effect of topical Wishca, Diclofenac and Capsaicin in therapeutic symptoms, outcomes and knee function in different grades of knee Osteoarthritis

Design
Randomized controlled trial; parallel groups, 45 patients patients were allocated to three treatment groups by simple randomisation using Random numbers table

Settings and conduct
A data review checklist was completed by patient's demographic data and clinical findings (including knee crepitation, effusion, range of motion (ROM) and ligament stability) Patients were asked to apply 1 mL of ointment 3 times a day, topically on the osteoarthritic knee. At the baseline, the end of week 1 and 4, with one week run in period before beginning the assessment we used the KOOS questionnaire (Knee injury and Osteoarthritis Outcome Score) and VAS to collect patient-reported knee symptoms and function. outcomes in treatment groups and different OA grades were compared eventually knee osteoarthritis grading according to Kellgren and Lawrence (K & L) radiologic system

Participants/Inclusion and exclusion criteria
patient with primary knee osteoarthritis, without any history of knee injury, recent arthroscopy, Intra-articular injection, malignancy acute psychological illness

Intervention groups
Group 1: patient receiving WishCa herbal cream produced in IMD Company (Dr. Kamkar International Laboratory) contains the active ingredient of 7 herbs; - Group 2: patent receiving capex 0.034%, produced by Barijessence inc. - Group 3: patent receiving Diclofenac Diethylammonium Salt Eq To diclofenac 1% gel produced by RAZAK Labs. Co.

Main outcome variables
symptoms and knee function (KOOS); pain (VAS); range of motion.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130228012654N2**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **retrospective**

Last update: **2020-06-02, 1399/03/13**
Update count: **0**

Registration date
2020-06-02, 1399/03/13

Registrant information

Name
Fatemeh Hosseinnezhad

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-09-23, 1396/07/01

Expected recruitment end date
2017-12-21, 1396/09/30

Actual recruitment start date
2017-09-23, 1396/07/01

Actual recruitment end date
2018-03-06, 1396/12/15

Trial completion date
2018-03-06, 1396/12/15

Scientific title

Comparison the therapeutic effect of topical Wishca,Diclofenac and Capsaicin in patient with knee Osteoarthritis

Public title
Comparing the effect of topical Wishca, Diclofenac and Capsaicin cream in knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
confirmed knee osteoarthritis according to American Rheumatology Association criteria history of knee pain ages 30 to 70 knee pain on most days of >40 mm on a 100 mm VAS on the worst knee giving informed consent
Exclusion criteria:
patient with other forms of arthritis (including secondary osteoarthritis, Rheumatic diseases a significant knee injury Having Low Back Pain and other referral pain to the knee History of arthroscopy in the previous 6 months, History of corticosteroid injection in the last 3 months History of knee surgery History of the knee clinical trials participation History of intra-articular injection of hyaluronic acid in the previoHistory of malignancyus 6 months open knee wound active dermatitis Infectious disease involving joints like TB or brucellosis acute psychological illness (especially depression) History of malignant neoplasm history of lower limb trauma leads to rupture of the meniscus, ligament, or capsule Patients with increased complaints and who are not satisfied with continuing medication
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Actual sample size reached: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomztion, a random sequence generated for three treatment groups. for this purpose, a point in random numbers table was selected and moving to the right, considering single digits, from numbers 1 to 3 assigned to group A: Wishca, numbers 4 to 6 to group B: Cepx and numbers 7 to 9 were assigned to group C: Diclofenac. Based on this sequence, participants entered three treatment groups. randomization unit: individual
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 Mashhad Islamic Azad University, Faculty of Medicine
Street address
Sarab street, Shahinfar faculty of medical science
City
Mashhad
Province
Razavi Khorasan
Postal code
9133736351
Approval date
2017-08-23, 1396/06/01
Ethics committee reference number
IR.IAU.MSHD.REC.1396.19

Health conditions studied

1

Description of health condition studied
knee osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
symptoms and function of affected knee
Timepoint
At the baseline, the end of week 1 and 4 with one week washout period
Method of measurement
KOOS questionnaire

2

Description
pain
Timepoint
At the baseline, the end of week 1 and 4 with one week washout period
Method of measurement
VAS visual analogue scale

3

Description
range of motion

Timepoint
At the baseline, the end of week 1 and 4 with one week washout period
Method of measurement
Angle measurement

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Wishca, patients receiving WishCa herbal cream produced in IMD Company (Dr. Kamkar International Laboratory) contains the active ingredient of 7 herbs; Patients were asked to apply 1 mL of ointment 3 times a day, topically on the osteoarthritic knee.
Category
Treatment - Drugs

2

Description
Intervention group 2: Capsaicin, patients receiving Capex 0.034%, produced by Barijessence inc ; Patients were asked to apply 1 mL of ointment 3 times a day, topically on the osteoarthritic knee.
Category
Treatment - Drugs

3

Description
Control group: Diclofenac patents receiving Diclofenac Diethylammonium Salt Eq To diclofenac 1% gel produced by RAZAK Labs. Co ; Patients were asked to apply 1 mL of ointment 3 times a day, topically on the osteoarthritic knee.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
outpatient Knee & Orthopedic clinic of Imam Reza Hospital of Mashhad
Full name of responsible person
Fatemeh Hosseinnezhad
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Imam Reza Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Vice Chancellor of Research, Faculty of Medicine, Mashhad Islamic Azad University
Proportion provided by this source
1
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
Islamic Azad University
Full name of responsible person
Fatemeh Hosseinnezhad
Position
medical doctor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The data would be delivered upon journal request
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable