

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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 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: patient receiving capex 0.034%, produced by Barijessence inc. - Group 3: patient 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 Hosseinneshad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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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 malignancy 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: Ceph 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 Hosseinezhad

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Imam Reza Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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?

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 Hosseinezhad

Position

medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

Family Physician

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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