

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

+98 51 2225 0042

##### Email address

hosseinneshad.fatemeh70@gmail.com

##### 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

##### Street address

Imam Reza Square

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

7134814734

##### Phone

+98 51 3713 2127

##### Email

hosseinezhad.fatemeh70@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Dr.Saeed Abtahi

##### Street address

Sarab street, Shahifar faculty of medicine

##### City

mashhad

##### Province

Razavi Khorasan

##### Postal code

9133736351

##### Phone

+98 51 3223 5175

##### Email

Abtahi@mshdiau.ac.ir

#### 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

##### Street address

00

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9183857838

**Phone**

00

**Fax****Email**

hosseinnezhad.fatemeh70@gmail.com

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Fatemeh Hosseinnezhad

**Position**

medical doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

sarab street, Faculty of Medicine, Mashhad Islamic Azad University

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9183857838

**Phone**

00

**Fax****Email**

hosseinnezhad.fatemeh70@gmail.com

## Person responsible for updating data

**Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Fatemeh Hosseinnezhad

**Position**

medical doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

Sarab Street, Faculty of Medicine, Mashhad Islamic Azad University

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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