

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jul 2026

### Comparison the effectiveness of two methods localized heat therapy and kldrab gel on symptoms and joint function in patients with knee erosion

#### Protocol summary

##### Study aim

Determination and comparison of the efficacy of topical heat therapy and kldrab gel on the symptoms and joint function of patients with knee erosion

##### Design

The controlled clinical trials, community-based and action-oriented, parallel group, randomized

##### Settings and conduct

An interventional study with three groups including two groups of control group and control group from patients with osteoarthritis in Imam Sajjad Dehdasat and Mofattah Yasouj clinics

##### Participants/Inclusion and exclusion criteria

The willingness of the patient to participate in the study, aged between 45 and 60 years, approved by the orthopedic surgeon, There is crepitus in knee active movement , morning stiffness less than 30 minutes, restriction of movement, knee pain on most days last month Exclusion criteria: withdrawal patient of continue cooperation, Migration of patients from the study, the patient's death

##### Intervention groups

gel kldrab and heat therapy

##### Main outcome variables

Pain and swelling and stinginess in patients with knee erosion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180802040671N1**

Registration date: **2018-08-28, 1397/06/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-08-28, 1397/06/06**

Update count: **0**

##### Registration date

2018-08-28, 1397/06/06

##### Registrant information

###### Name

Moslem Aryana

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 74 3226 8646

###### Email address

moslem.ariana@yums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-08-22, 1397/05/31

##### Expected recruitment end date

2018-09-21, 1397/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effectiveness of two methods localized heat therapy and kldrab gel on symptoms and joint function in patients with knee erosion

##### Public title

Comparison the effectiveness of two methods localized heat therapy and kldrab gel on symptoms and joint function in patients with knee erosion

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patient's willingness to participate in the study Age range from 45 to 60 years Certified orthopedic practitioner Creatine keratinization in knee joint active movement, morning dryness less than 30 minutes, movement constraints, knee pain in most days of the last month  
**Exclusion criteria:**  
Patient's refusal to continue cooperation, immigration of the patient from the study site Patient death Immigration of the patient from the study site

#### Age

From **45 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

No information

#### Sample size

Target sample size: **114**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Sampling will be simple random and will continue until reaching the sample size. The samples will be assigned to two experimental groups (the Kelderab gel intervention group, the Therapy group) and a control group (three groups) based on randomized block assignment.

#### 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 yasuj University of Medical Sciences

##### Street address

Yasuj motahari blvd

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyer-Ahmad

##### Postal code

7591741417

#### Approval date

2018-07-21, 1397/04/30

#### Ethics committee reference number

IR.YUMS.REC.1397.039

## Health conditions studied

### 1

#### Description of health condition studied

KNEE EROSION

#### ICD-10 code

M19.9

#### ICD-10 code description

Osteoarthritis, unspecified site

## Primary outcomes

### 1

#### Description

KNEE EROSION

#### Timepoint

1MONTHS

#### Method of measurement

QUESTIONNAIRE

## Secondary outcomes

### 1

#### Description

STINGINESS

#### Timepoint

1MONTHS

#### Method of measurement

QUESTIONNAIRE

### 2

#### Description

PAIN

#### Timepoint

1 MONTH

#### Method of measurement

QUESTIONNAIRE

### 3

#### Description

SWELLING

#### Timepoint

1MONTHS

#### Method of measurement

QUESTIONNAIRE

## Intervention groups

### 1

#### Description

The protocol of using Kelderab gel: In case group 1, a combination topical gel in the knee area is used before the application of topical gel in case group 1, symptoms and performance status are assessed by the researcher using the wear and tear injuries inventory questionnaire. In the case group 1, the ointment containing eucalyptus,

menthol and camphor (clodrub ointment, manufactured by Gol Dara Company, Iran) is supplied to the patients. Each patient should use it daily twice a day. Treatment lasts for 4 weeks. Patients undergo weekly evaluations using wear and tear injuries questionnaire.

#### Category

Treatment - Drugs

## 2

#### Description

Prototype of hot water bag: In group 2, a hot water bag is used in the knee area at 55 ° C. Before the intervention, symptoms and functional status of the patients are examined using a questionnaire together with the researcher. Subsequently, the intervention group Treatment with a warm water bag daily is treated twice daily for up to 20 minutes each time for 4 weeks. Patients are evaluated weekly by using a questionnaire.

#### Category

Treatment - Devices

## 3

#### Description

Control group: no interventionControl group:There will be no intervention in the control group. Patients in this group received routine care and only the research tools will be completed.

#### Category

Other

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

Clinic Imam Sajad of Dehdasht

##### Full name of responsible person

Moslem Ariana

##### Street address

Dehdasht .Golzar Street

##### City

Dehdasht

##### Province

Kohgilouyeh-va-Boyrabad

##### Postal code

75711845449

##### Phone

+98 74 3226 5903

##### Email

Moslem.Ariana@Yums.Ac.Ir

## 2

#### Recruitment center

##### Name of recruitment center

Clinic Shahid Mofateh of Yasuj City

##### Full name of responsible person

Moslem Ariana

##### Street address

Yasuj Side Shahid Behshte Hospital

#### City

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#### Province

Kohgilouyeh-va-Boyrabad

#### Postal code

7591741417

#### Phone

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#### Email

Moslem.Ariana@Yums.Ac.Ir

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Hossein Marioryad

##### Street address

Martyr Motahhari

##### City

Yasouj

##### Province

Kohgilouyeh-va-Boyrabad

##### Postal code

7571845449

##### Phone

+98 74 1223 1556

##### Email

Moslem.ariana@yums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Yasouj 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

Yasouj University of Medical Sciences

##### Full name of responsible person

Moslem Ariana

##### Position

Student

##### Latest degree

Bachelor

**Other areas of specialty/work**

Nursery

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**Email**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Shahla Najafi

**Position**

Instructor

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Martyr Motahhari

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**Person responsible for updating data****Contact****Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Moslem Ariana

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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+98 987432268646

**Email**

Moslem.Ariana@Yums.Ac.Ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

**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**

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**

The data is analyzed and the results are published as a paper

**When the data will become available and for how long**

one year

**To whom data/document is available**

For scholars working in academia and academia

**Under which criteria data/document could be used**

For use in other studies

**From where data/document is obtainable**

By email and with the researcher

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

Contact the researcher as soon as possible

**Comments**