

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-Boyrahmad

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

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591741417

Phone

+98 74 3336 4721

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-Boyrahmad

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

Street address

Golzar Street

City

Dehdasht

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7571845449

Phone

+98 74 3226 8646

Email

MOSKEM.ARIANA@YUMS.AC.IR

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

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7571845449

Phone

+98 74 1223 1556

Email

MOSLEM.ARIANA@YUMS.AC.IR

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

Golzar Street

City

Dehdasht

Province

Kohgilouyeh-va-Boyrahmad

Postal code

۷۵۷۱۸۴۵۴۴۹

Phone

+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