

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

clinical trial study of iontophoretic effects of kimiainca gel on patients with Knee Osteoarthritis in 2022: pilot study

Protocol summary

Study aim

Evaluation of iontophoretic effects of kimiainca gel on patients with Knee Osteoarthritis

Design

Two arm parallel groups randomized trial with blinded postoperative care and outcome assessment

Settings and conduct

Patients with osteoarthritis referred to the clinic of Sayad Shirazi Medical Center of Golestan University of Medical Sciences, patients aged 45 to 75 years will be randomly assigned to one of the experimental groups, double-blind, placebo-controlled. This study was performed on 45 patients with a diagnosis of osteoarthritis of the knee who were voluntarily and randomly divided into 3 groups of 15 for 6 sessions for two weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of osteoarthritis of the knee based on examination by a specialist Age between 45 and 75 male or female Voluntary participation and written consent exclusion criteria: Existence of telofemoral or hip osteoarthritis, history of any knee fracture or surgery history of inflammatory joint disease history of intra-articular injection during the last six months regular use of steroidal and non-steroidal anti-inflammatory drugs and anti-inflammatory drugs during the previous two months

Intervention groups

Group 1: treated with iontophoresis and placebo gel (n = 15) (control group) Group 2: treated with iontophoresis and chimeranica gel (containing a mixture of plant extracts) (n = 15) Group 3: Treated with chimarnica gel and placement of electrode without iontophoresis in topical application (n = 15)

Main outcome variables

pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220411054495N1**

Registration date: **2022-04-17, 1401/01/28**

Registration timing: **prospective**

Last update: **2022-04-17, 1401/01/28**

Update count: **0**

Registration date

2022-04-17, 1401/01/28

Registrant information

Name

hassan mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3245 1434

Email address

mirzaei22@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2023-06-22, 1402/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

clinical trial study of iontophoretic effects of kimiainca gel on patients with Knee Osteoarthritis in 2022: pilot study

Public title

Evaluation of iontophoretic effects of kimiaınca gel on patients with Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of osteoarthritis of the knee based on examination by a specialist Age between 45 and 75 male or female Voluntary participation and written consent

Exclusion criteria:

Existence of telofemoral or hip osteoarthritis, history of any knee fracture or surgery history of inflammatory joint disease history of intra-articular injection during the last six months regular use of steroidal and non-steroidal anti-inflammatory drugs and anti-inflammatory drugs during the previous two months

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

The random assignment list will be computer generated with a 1:1 allocation, stratified by recruitment site, using a random block size of four. Using concealed in sequentially numbered, sealed, opaque envelopes (SNOSE), participants will enter the blocks in such a way that an equal number of each assigned group. Allocation will be done by randomly selecting one of the arrangements and assigning the next part of the participants to the study groups according to the specified sequence. And kept by the hospital pharmacist of the center

Blinding (investigator's opinion)

Double blinded

Blinding description

To maintain blindness in patients, the drug and placebo are the same in shape and appearance. Also, the evaluator is not aware of the type of drugs in the intervention groups, so that multi-digit numerical codes are written on the drug packages that only the main person in charge of the research is aware of.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

School of Medicine, Golestan University of Medical Sciences, Gorgan, Iran

City

Gorgan

Province

Golestan

Postal code

۷۴۵۱۵ ۴۹۳۴۱

Approval date

2022-02-06, 1400/11/17

Ethics committee reference number

IR.GOUMS.REC.1401.003

Health conditions studied

1

Description of health condition studied

osteoarthritis

ICD-10 code

M15.9

ICD-10 code description

Polyosteoarthritis, unspecified

Primary outcomes

1

Description

pain

Timepoint

Before and after intervention

Method of measurement

KOOS questionnaire (Knee Injury and Osteoarthritis Outcome Score)

Secondary outcomes

1

Description

blood pressure

Timepoint

Before and after intervention

Method of measurement

Mercury sphygmomanometer

2

Description

CRP Test (C-Reactive Protein)

Timepoint

Before and after intervention

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: Treated with iontophoresis and Kimiarnika gel (containing a mixture of plant extracts) (n = 15) Intervention group: treated with iontophoresis and chimiarnica gel (containing a mixture of plant extracts) (n = 15).in iontophoresis using galvanic current (low current and low voltage) can accelerate the penetration of the drug into the tissues. The ointment used in this combination is called Kimiarnica and all the mentioned compounds are according to the pharmacopoeia. All the ingredients used in this ointment are effective and have been used medicinally and have not had any side effects in clinical trials. These compounds are prepared by a reputable pharmaceutical factory and have the necessary and approved health licenses. Preparation formula for 1000 g = 200 g of marigold flower extract + 150 g of devil's claw extract + 150 g of ginger + + 100 g of capsaicin (pepper) + 150 g of nanocurcumin powder + 50 g of bee venom + 50 g of cannabidiol + base cream 150 g for Formulation The following steps are performed: The method of preparing the base The formulation is the method of melting. First, the semi-solid and solid materials that make up the base, which include Vaseline, etc., are melted and the temperature of the melt mixture is raised to 70 ° C and then, until it reaches stirring was continued at 40 °C. At this step, the effective compounds and concentrated extracts, which were semi-solid, were each geometrically separated from some of the base and added to the rest of the base. The mixing process continued until the product was uniformed and then the formulation was prepared. then packed into 15 g tubes. Then the uniformity and stability of the formulation against heat and cold as well as the study of the formulation in terms of pH changes are evaluated. How to intervene: First, to reduce skin resistance, the inside of the knee was washed with soap and water. In this group, while the cathode pole was placed on the inner part of the knee and the anode on the opposite side, the galvanic current was established for 20 minutes with an intensity of 5 mA. In the first group, after the gel was spread on the skin of the inner area of the knee, the cathode electrode was placed as the active pole on that area and the anode electrode was placed on the opposite side, and the facial treatment was performed for 20 minutes at 5 mA. The amount of drug used was large enough to cover the skin of the active electrode in a thin layer. Number of patients: 15 patients with osteoarthritis of the knee, in the age range of 45-75 years. Number of uses: 6 sessions Duration: 20 minutes to use: Topical Manufacturer: All compounds are used by reputable

pharmaceutical companies and have the necessary and approved health licenses.

Category

Treatment - Drugs

2

Description

Intervention group: Kimiarnika gel and electrode placement without iontophoresis (n = 15). Intervention group: treated with iontophoresis and chimiarnica gel (containing a mixture of plant extracts) (n = 15).in iontophoresis using galvanic current (low current and low voltage) can accelerate the penetration of the drug into the tissues. The ointment used in this combination is called Kimiarnica and all the mentioned compounds are according to the pharmacopoeia. All the ingredients used in this ointment are effective and have been used medicinally and have not had any side effects in clinical trials. These compounds are prepared from a reputable pharmaceutical factory and have the necessary and approved health licenses. Preparation formula for 1000 g = 200 g of marigold flower extract + 150 g of devil's claw extract + 150 g of ginger + + 100 g of capsaicin (pepper) + 150 g of nanocurcumin powder + 50 g of bee venom + 50 g of cannabidiol + base cream 150 g for Formulation The following steps are performed: The method of preparing the base The formulation is the method of melting. First, the semi-solid and solid materials that make up the base, which include Vaseline, etc., are melted and the temperature of the melt mixture is raised to 70 °C and then, until it reaches stirring was continued at 40 °C. At this step, the effective compounds and concentrated extracts, which were semi-solid, were each geometrically separated with some of the base and added to the rest of the base. The mixing process continued until the product was uniformed and then the formulation was prepared. then packed in 15 g tubes. Then the uniformity and stability of the formulation against heat and cold as well as the study of the formulation in terms of pH changes are evaluated. How to intervene: First, to reduce skin resistance, the inside of the knee was washed with soap and water. In the second group, Kimiarnika gel was massaged on the skin of the inner part of the knee and then, as in the previous group, electrode was applied on the knee with the device on and without output for 20 minutes. The amount of drug used was large enough to cover the skin of the active electrode in a thin layer. Number of patients: 15 patients with osteoarthritis of the knee, in the age range of 45-75 years. Number of uses: 6 sessions Duration: 20 minutes How to use: Topical

Category

Treatment - Drugs

3

Description

Control group: Treated with iontophoresis and placebo gel (n = 15) In this method, iontophoresis with galvanic current (low current and low voltage) is used. Placebo gel with a combination of base cream and Vaseline is used. All the materials used in this gel are of medicinal type

and have no side effects in clinical trials. These compounds are prepared by a reputable pharmaceutical factory and have the necessary and approved health licenses. How to intervene: First, to reduce skin resistance, the inside of the knee was washed with soap and water. In this group, while the cathode pole was placed on the inner part of the knee and the anode on the opposite side, the galvanic current was established for 20 minutes with an intensity of 5 MA. In the first group, after the placebo gel was spread on the skin of the inner area of the knee, the cathode electrode was placed as the active pole on that area and the anode electrode was placed in front of it and treated for 20 minutes at 5 mA. Took. The amount of drug used was large enough to cover the skin of the active electrode in a thin layer. All patients were treated for 6 sessions and in order to evaluate the effectiveness of each treatment method, in the two stages before and after 6 sessions of treatment (Knee injury and Osteoarthritis KOOS) outcome Score, which includes assessment of pain, joint dryness and function. Physical patients is used. Number of patients: 15 patients with osteoarthritis of the knee, in the age range of 45-75 years. Number of uses: 6 sessions. Duration: 20 minutes. How to use: Topical Manufacturer: All compounds from reputable pharmaceutical companies and have the necessary and approved health licenses is used.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ischemic Disorders Research Center, Golestan
University of Medical Sciences

Full name of responsible person

Dr. Vahid Khor

Street address

Shastkola Road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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?

Yes

Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Vahid Khor

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Name of organization / entity

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Dr. Vahid Khor

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Associate professor

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Other areas of specialty/work

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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

There is no more information

Study Protocol

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available