Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the therapeutic effect of 5% ibuprofen nanoemulsion gel and commercial ibuprofen gel on knee osteoarthritis pain

Protocol summary

Study aim
Clinical trial to compare the effectiveness of nanoemulsion and commercial formulations of ibuprofen

Design
This study is designed to evaluate the efficacy and short-term safety of topical use of 5% Ibuprofen-nanoemulsion and 5% commercial gel in 124 patients with knee osteoarthritis. This is a Phase III, randomized, double-blind, parallel-group, two-arm, 4-week study. Excel software rand function is used for randomization.

Settings and conduct
It will be performed in the clinic of the orthopedic center of Shafaiehian Hospital. Commercial ibuprofen gel will be included in similar packages of nanoemulsion gel containing ibuprofen. The randomized code will be written on the medicine package. The patient, researcher, physician, and data analyst are unaware of the type of drug.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The diagnosis of knee osteoarthritis via clinical and radiological examinations, Having mild to moderate knee osteoarthritis, Written informed consent. Non inclusion criteria: Severe knee pain, history of disease-related surgery such as joint replacement and repair, inflammatory atropathy, metabolic bone disease, knee fracture, history of open wound in the affected knee.

Intervention groups
Intervention group 1: Treatment group with 5% ibuprofen-nanoemulsion gel. Intervention group 2: 5% commercial ibuprofen gel. For 4 weeks, patients are recommended to use their prescribed drug three times per day as a fingertip unit.

Main outcome variables
Pain; Skin irritation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150902023864N3**
Registration date: **2021-02-28, 1399/12/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-28, 1399/12/10**
Update count: **0**

Registration date
2021-02-28, 1399/12/10

Registrant information

Name
Amir Amani

Name of organization / entity
Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-02-19, 1399/12/01

Expected recruitment end date
2021-07-21, 1400/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the therapeutic effect of 5% ibuprofen nanoemulsion gel and commercial ibuprofen gel on knee

osteoarthritis pain

Public title

Effect of Ibuprofen Nanoemulsion Gel on Knee Osteoporosis pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Unilateral or bilateral knee osteoarthritis with radiographic evidence according to American College of Rheumatology criteria and the International Osteoarthritis Research Society which is diagnosed through physical examination by the physician Having mild to moderate knee osteoarthritis pain Written informed consent to participate in the study

Exclusion criteria:

Very severe knee pain Recent lower limb injury or surgery such as repair and joint replacement Inflammatory arthritis Metabolic bone disease Fracture and/or dislocation of knee History of an open wound in the affected knee History of adverse reactions to NSAIDs Diabetes and Lupus disease Corticosteroid injection into the knee within 30 days of intervention Multiple sclerosis (MS) The dermatologic disorder which affected the surrounding skin of the knees Uncontrolled heart failure High blood pressure Chronic renal failure Respiratory diseases Cancer History of alcohol or drug abuse History of neurological disorders affecting sensory, motor or cognitive function

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **124**

More than 1 sample in each individual

Number of samples in each individual: **2**

Both knees with osteoarthritis are considered as two examples

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed by means of a computer randomization system based on fragmented, balanced randomization. In this method to increase the probability of equal numbers of people in both groups, blocks in the form of: AABB-ABAB-ABBA-BBAA-BABA-BAAB are defined as A containing commercial ibuprofen gel and B nanoemulsion gel containing ibuprofen.From 0 to 5 randomizations will be done using digitally randomized codes. The sequence is constructed in such a way that, with 31 sample volumes, 124 (4□31) codes will be selected for participants using Excel. Group A: Commercial ibuprofen gel, Group B: Ibuprofen nanoemulsion gel Block sizes: 4 Actual list length: 124 In order to concealment the randomization, the container containing the formulation will be the same in terms of shape, only a code will be written on each package so that the prescriber or the patient will be completely unaware of the contents of the container.

Blinding (investigator's opinion)

Double blinded

Blinding description

Commercial ibuprofen gel will be included in similar packages of nanoemulsion gel containing ibuprofen. The randomized code will be written on the medicine package. However, due to the difference in the smell of these two drugs, we try to prevent patients from being able to compare drugs by conducting separate patient interviews. Based on the random number written on the prescription of the patient, pharmacy officials are asked to deliver the medicine to the patients. The researcher will not know which patient was taking which medication. Also, the treating physician will not be aware of the patient's medication. The patient is requested to deliver the used medicine container to the hospital pharmacy at the next visit and to receive the same number from the pharmacy at the next visit. During the second visit of patients, empty containers of medicines will be collected from the pharmacy every day and stored in a special comedy. The statistical data analyzer will not be able to distinguish between the information obtained from the patients of both groups and the information will be completely blinded to their service.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.TUMS.TIPS.REC.1399.118

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
Pain score based on visual analogue scale and Western Ontario and McMaster Universities Osteoarthritis Index questionnaire
Timepoint
Patients are assessed prior to enrollment and, then, 2 and 4 weeks subsequent to the intervention for knee pain.
Method of measurement
Visual analogue scale on a 10 cm scale and Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

Secondary outcomes

1

Description
skin irritation
Timepoint
24-48 hours in initial use, then two-and four-week visits.
Method of measurement
Questions are asked by phone during the first 24-48 hours, so any skin problems are requested and checked by the doctor during each visit.

Intervention groups

1

Description
Intervention group 1: Nanoemulsion gel containing 5% ibuprofen; Patients are treated with this formulation for 4 weeks and three times a day in the size of a fingertip (equivalent to 100 mg), which has already been prepared and animal studies have been performed.
Category
Treatment - Drugs

2

Description
Intervention group 2: commercial ibuprofen 5% gel; Patients are treated with a commercial gel available in the pharmacy in the size of a fingertip three times a day, for 4 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafa Yahyaian hospital
Full name of responsible person
Amir Amani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
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Qods street; Keshavarz boulevard
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Web page address
https://www.tums.ac.ir/
Grant name
8 articles Grant
Grant code / Reference number
99-2-229-47907
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Fariba Esmaeili

Position
post doc

Latest degree
Ph.D.

Other areas of specialty/work
Medical Nanotechnology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

All data potentially can be shared after making participants unidentifiable

When the data will become available and for how long

Nearly in a year

To whom data/document is available

All people

Under which criteria data/document could be used

There is no condition

From where data/document is obtainable

They can email to the researcher

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

We do our best to deliver the data in a month

Comments