Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of exercise therapy and drug in relieving pain and disability caused by osteoarthritis of the knee

Protocol summary

Study aim
The effect of exercise therapy on pain relief due to knee osteoarthritis
Design
Clinical efficiency with control group, parallel groups, without blindness, randomized, letters card was used for randomization .50 patients were included in the study and followed up for 3 months.
Settings and conduct
This study will be conducted in Yasa hand-held pain clinic in Fasa, patients less than 30 years and over 70 years old and patients who are not satisfied with participation in the study will be excluded from the results of unexplored outcomes and according to ODI patients will announce their pain improvement.
Participants/Inclusion and exclusion criteria
The criteria for entering the study are age 30 to 70 years with the severity of knee VAS pain above 3, lack of knee-related rheumatology disease such as gout, rheumatological orthotics, RA and lack of uncontrollable underlying disease
Intervention groups
In this study, the effect of exercise on the improvement of knee pain due to knee osteoarthritis will be determined. The first group will receive only medication and the second group will receive medication and exercise.
Main outcome variables
Primary disability, patient satisfaction, pain improvement

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220830055831N1**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **retrospective**
Last update: **2022-09-10, 1401/06/19**
Update count: **0**
Registration date
2022-09-10, 1401/06/19

Registrant information
Name
Fateme Zeinali
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-08-30, 1401/06/08
Expected recruitment end date
2022-09-05, 1401/06/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of exercise therapy and drug in relieving pain and disability caused by osteoarthritis of the knee

Public title
The effect of exercise therapy and drug in relieving pain and disability caused by osteoarthritis of the knee
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

age 30 to 70 years the severity of knee VAS pain above 3
Exclusion criteria:
Knee-related rheumatology such as gout, rheumatological arthritis, RA No uncontrollable underlying disease History of knee surgery

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: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will prepare a sample size of 50 cards, on 25 cards, we will write the letter a and 25 of the rest, and put them in the envelope in the package, and then we ask the patient to select one of the cards at the time of referral. If the patient has an a card, the intervention group and if the owner of the b card is placed in the control group.

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 Fasa University of Medical Sciences

Street address
Ibn Sina Square

City
Fasa

Province
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Postal code
7461459331

Approval date
2022-08-30, 1401/06/08

Ethics committee reference number
IR.FUMS.REC.1401.075

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 in oswestry Disability index

Timepoint
Evaluation of pain improvement 6 weeks after exercise

Method of measurement
Oswestry Disabylity Index Questionnaire

Secondary outcomes

1

Description
Patient satisfaction score from 0 to 10

Timepoint
Pain score after 6 weeks of exercise

Method of measurement
Patients were asked to tell their satisfaction score from exercises from 0 to 10.

Intervention groups

1

Description
Intervention group:The intervention group evaluated 25 patients with knee pain by giving me exercise strength, hydrotherapy, aerobic exercise and they are asked to do it 3 times a day for 6 weeks every 10 minutes.This group also use uniflex once a day, wishca cream three times a day and meloxicam tablets 15 mg every 12 hours in case of pain uniflex uniflex tablets containing calcium carbonate, methylsulfonylmethane , vitamin D and K , magnesium and zinc . Methylsulfonylmethane is anti-inflammatory and antioxidant and has been shown to have cartilage and collagen-making effects, which is useful for our study due to wear, which is cartilage analysis.

Category
Rehabilitation

2

Description
Control group: The control group also use uniflex tablets once a day, wishca cream three times a day and meloxicam tablets 15 mg every 12 hours in case of pain, uniflex uniflex tablets containing calcium carbonate, methylsulfonylmethane, vitamin D and K, magnesium and zinc. Methylsulfonylmethane is anti-inflammatory

and antioxidant and has been shown to have cartilage and collagen-making effects, which is useful for our study due to wear, which is cartilage analysis.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Vali-Asr Fasa Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Fasa University of Medical Sciences

Full name of responsible person
Bordbar Zare

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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
Fasa 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
Fasa University of Medical Sciences

Full name of responsible person
Fateme Zeinali

Position
intern

Latest degree
Medical doctor

Other areas of specialty/work
Medical Education

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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
Only a portion of data, such as information about the original outcome or the like, can be shared

When the data will become available and for how long
Start access 6 months after printing the results

To whom data/document is available
Academic and Scientific Institutions

Under which criteria data/document could be used
Data usage can be used for complementary work and expanding research

From where data/document is obtainable
fateme zeinali 09172516706

What processes are involved for a request to access data/document
The applicant can access the information after contacting Fatemeh Zeinali

Comments