IRCT | Comparison between the efficacy of ultrasound-guided dextro... https://irct.behdasht.gov.ir/trial/66819

Comparison between the efficacy of ultrasound-guided dextrose 25% hypertonic prolotherapy and intraarticular normal saline injection on pain, functional limitation and range of motion; in knee osteoarthritis patients

More options

Protocol summary

Study aim

Comparison of the effect of 25% hypertonic dextrose prolotherapy injection under ultrasound guidance with intra-articular injection of normal saline under ultrasound guidance in patients with chronic knee pain referred to Shiraz medical science training centers in improving pain and function and knee range of motion

Design

double-blind randomized clinical trial with a control group

Settings and conduct

The patient select from emam reza clinic and rajaee hospital who has knee OA.then patient divided into two groups and after obtaining written consent the study begins. in intervention group hypertonic dextrose is injected and in control group normalsaline is injected then we measure its effect on reducing pain and improving patient function and knee range of motion

Participants/Inclusion and exclusion criteria

The entry conditions include the age of the patients, patients 55-75 years old with pain or limitation of the range of motion of the knee for more than three months. Gender: male or female. Anterolateral knee x-ray taken in the last 3 months while standing. exclusion conditions: patients with inflammatory diseases and vascular collagen such as lupus and suspicion of knee infection, patients with coagulation disorders, patients with active lumbosacral radiculopathy and severe deformity of the spine and lower limbs, nervous system disorders, being pregnant , diabetes, A history of surgery on the knee, injection CS in the last two months, or intra-articular injection of hyaluronic acid in the last 12 months, or replacement of the knee joint, use of opioid drugs, body mass index above 40 should not be included in the study.

Intervention groups

Intervention group: The group that received 25% dextrose medicine intra-articularly in the knee. Control group: The group that receives normal saline intra-articularly.

Main outcome variables

Pain, Activity of daily living, knee range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221111056470N1**
Registration date: **2022-12-10, 1401/09/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-10, 1401/09/19**
Update count: **0**

Registration date

2022-12-10, 1401/09/19

Registrant information

Name
Nafiseh Birang
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3624 1170
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nafis_bg@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-16, 1401/08/25

Expected recruitment end date

2022-12-16, 1401/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the efficacy of ultrasound-guided dextrose 25% hypertonic prolotherapy and intraarticular normal saline injection on pain, functional limitation and range of motion; in knee osteoarthritis patients

Public title

Comparison between the efficacy of ultrasound-guided dextrose 25% hypertonic prolotherapy and intraarticular normal saline injection on pain, functional limitation and range of motion; in knee osteoarthritis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria: aged 55 to75 years; both genders; knee radiography anterior standing view have been for the last one month; have symptoms of osteoarthritis

include pain, limitation in knee range of motion , and knee joint dryness for at least a month without any extra-articular involvement.
Exclusion criteria:
Inflammatory and vascular collagen diseases such as lupus and suspected knee infection, patients with coagulation disorders, patients with active lumbosacral radiculopathy and severe deformity of the spine and lower limbs, peripheral and central nervous system disorders, pregnancy, diabetes, history of surgery on the knee, injection of steroid drugs in the last two months or intra-articular injection of hyaluronic acid in the last 12 months or replacement of the knee joint, use of opioid drugs, body mass index over 40

Age

From **55 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

To match patients in the intervention and control groups, patients are randomly assigned to one of two treatment groups. The random allocation method in this study will be the permutation blocks randomization method with 4 samples in each block and a random list of data will be obtained by using Random Allocation software. We will have two lists of 25patients, including the two intervention and control groups, at random. For concealment, method of random sequencing is given to another person who is unaware of the research process, and the questionnaires are completed by a person unaware of the division of groups

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: The participant is explained that if they are interested, they can join our research project. two methods used to reduce patient pain input study are explained to the patient. Benefits and possible complications of both methods are described to the patient and the patient is told to randomly fall into one of the intervention groups. If the patient is accepted to admit the study, by random allocation soft ware, the patient falls in to one of two groups. Clinical car giver: we teach the caregiver how to complete the questionnaier. This person is not aware of receiving patient intervention. Researcher: In this study does not have the ability to blind the reseacher because the researcher performs both intervention himself and is aware of receiving each intervention in the group. The outcome assessor of the complete questionnaires is given to person who is not aware of the interventions performed and he/she is asked to determine the level of performance in each person according to the questionnaires. Date analyzer: questionnaire are finally given to a person to review the information. This person doesn't know any of the steps of the work, how to classify and the intervention performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
No. 103., Sadi Dead End., Bijan Alley., Hakim Nezami Ave

City
Esfahan

Province
Isfehan

Postal code
8175979967

Approval date

2022-11-12, 1401/08/21

Ethics committee reference number

IR.SUMS.MED.REC.1401.246

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 scale

Timepoint

Just before the intervention & 2,4,8 weeks later.

Method of measurement

Visual Analogue Scale,Western Ontario and McMaster Universities Arthritis Index (WOMAC)

2

Description

Knee flexion degree

Timepoint

Just before the intervention & 2,4,8 weeks later.

Method of measurement

goniometry

Secondary outcomes

1

Description

functional limitation

Timepoint

Just before the intervention & 2,4,8 weeks later.

Method of measurement

Oxford knee score and Western Ontario and McMaster Universities Arthritis Index (WOMAC)

Intervention groups

1

Description

Intervention group: The group that received 25% dextrose hyper-tonic intra-articularly under ultrasound guidance.

Category

Treatment - Drugs

2

Description

Control group: The group that received normal saline intra-articularly under ultrasound guidance.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam reza rehabilitation clinic

Full name of responsible person
Mani Ramzi

Street address
Namazi square

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Shiraz

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Fax

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2

Recruitment center

Name of recruitment center
Rajai hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Yunes Ghasemi

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Nafiseh Birang

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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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 available data can be shared after making people unidentifiable.
When the data will become available and for how long	Start access period one year after publishing the results.
To whom data/document is available	everyone can access to this information.
Under which criteria data/ document could be used	if the information in this study helps to improve the science process.
From where data/document is obtainable	nafis_bg@yahoo.com 00989132052155
What processes are involved for a request to access data/ document	After sending the desired message, all authors of the study will be consulted all information will be sent within a maximum of three weeks if permitted
Comments	

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