

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of 50% dextrose and corticosteroid injections in the treatment of osteoarthritis of the first metatarsophalangeal joint

Protocol summary

Study aim

Comparison of the effectiveness of Corticosteroid injection(methylprednisolone) with Dextrose 50% (prolotherapy) in osteoarthritis of the first metatarsophalangeal joint

Design

Randomized clinical trial, double blind, Block randomization

Settings and conduct

This study will performed on patients who referred to physical medicine clinics in Shiraz in 2021, double blind ,and the patient and therapist are not aware of the selected drug

Participants/Inclusion and exclusion criteria

Patients aged 30 to 65 years with complaints of pain in the first metatarsophalangeal joint, Exclusion criteria: Rheumatic diseases, diabetes, bone infection, surgery in the first metatarsophalangeal joint, coagulation problems, pregnancy, any injection in the first metatarsophalangeal joint of the foot in the last 6 months

Intervention groups

The first group of 16 people receive corticosteroid injection (methylprednisolone) and the second group of 16 people receive 50% dextrose injection (prolotherapy).

Main outcome variables

Based on criteria: VAS questionnaire (Visual analog scale) MOXFQ (Manchester -Oxford Foot Questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210308050637N1**

Registration date: **2021-03-14, 1399/12/24**

Registration timing: **prospective**

Last update: **2021-03-14, 1399/12/24**

Update count: **0**

Registration date

2021-03-14, 1399/12/24

Registrant information

Name

Batul safarri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5372 2583

Email address

betinaz8693@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of 50% dextrose and corticosteroid injections in the treatment of osteoarthritis of the first metatarsophalangeal joint

Public title

The effect of corticosteroid and dextrose injections in the treatment of osteoarthritis of the big toe joint

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain in first metatarsophalangeal joint of foot No response to conventional treatments

Exclusion criteria:

Rheumatologic disease Diabetes mellitus Bone infection Surgery in the treated area Coagulative disorder Pregnancy Any injection in first metatarsophalangeal joint of foot in the last 6 months

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Each of the 32 patients will be explained that they will be randomly placed in one of the intervention groups. If the patient is accepted to enter the study using a complete randomized block with Random allocation software, the patient will be placed in one of the two groups. Then, Opaque sealed envelopes are used to hide random sequences. The drugs are labeled A and B and are given to patients at random. In the end, 16 people will receive methylprednisolone and 16 people will receive 50% dextrose.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blinded. Patients are unaware of drugs for other groups. The results analyzer is also unaware of the interventions performed in each group and for each patient

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

Zand ave, Shahid Faghihi hospital, Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-12-01, 1398/09/10

Ethics committee reference number

IR.SUMS.MED.REC.1398.489

Health conditions studied

1

Description of health condition studied

Osteoarthritis of the first metatarsophalangeal joint (Hallux rigidus)

ICD-10 code

M20.2

ICD-10 code description

Hallux rigidus

Primary outcomes

1

Description

Pain level

Timepoint

Measurement of pain at the beginning of the study, 1 week, 4 weeks and 8 weeks after injection

Method of measurement

Visual Analog Scale

2

Description

Function

Timepoint

Measurement of pain at the beginning of the study, 1 week, 4 weeks and 8 weeks after injection

Method of measurement

Manchester-Oxford Foot Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 16 patient, receive corticosteroid (methylprednisolone) injection. The injection will be done at one time. Dose of methylprednisolone acetate (Exir) 1 cc + 1 cc Lidocaine 2%, the injection will be under sterile conditions with a 2 cc syringe (23 gauge), which is inserted from the medial side of the joint and the injection will be done at the top and bottom

Category

Rehabilitation

2**Description**

Intervention group 2: 16 patients receive dextrose 50% (prolotherapy). The injection will be done at one time. Prolotherapy with 1 cc dextrose 50% (Shahid Ghazi) + 1 cc Lidocaine 2%, the injection will be under sterile conditions with a 2 cc syringe (23 gauge), which is inserted from the medial side of the joint and the injection will be done at the top and bottom

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Faghihi Hospital

Full name of responsible person

Mohammadjavad Hadianfard

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Zand St.

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hadianj@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaianzadeh

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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

Mohammadjavad Hadianfard

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Mohammadjavad Hadianfard

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Batul Safarri
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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 after unidentification can be shared

When the data will become available and for how long

Start access after publishing results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Will be answered depending on the case

From where data/document is obtainable

betinaz8693@gmail.com

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

Send the email containing your request to the email address betinaz8693@gmail.com , it will be answered as soon as possible

Comments