

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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:**  
Rhomatologic disease Diabetes mellitus Bone infection Surgury in thr 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 firs 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 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 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

**Street address**

Zand St.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

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+98 71 3235 1087

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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  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Physical Medicine  
**Street address**  
Shahid Faghihi hospital, Zand Ave, Shiraz town  
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**Email**  
betinaz8693@gmail.com

## 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