

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison efficacy of extra articular dextrose prolotherapy with Routine physiotherapy in chronic ankle tendinopathy

Protocol summary

Study aim

Comparison extraarticular dextrose with physiotherapy in chronic ankle tendinopathy

Design

Tow arm parallel group randomized trial

Settings and conduct

physiotherapy treatment study group that include 10 sessions of treatment with hotpack,ultrasound,TENS in the affected area is performed and in the other group 2 injections of extra articular prolotherapy with dextrose 12%and lidocaine2% 5 cc in the ankle in 501 hospital

Participants/Inclusion and exclusion criteria

20<age<50 MRI evidence of tendinopathy conscious patient satisfaction symptoms more than 6 month rheumatological disease diabetes localized local infection allergy to the drug to be injected use of anticoagulants INR disrupted immunodeficiency acute fracture

Intervention groups

20patient were in the dextrose injection and 20 were in physiotherapy group. physiotherapy treatment study group that include 10 sessions of treatment with hotpack,ultrasound,TENS in the affected area is performed and in the other group 2 injections of extra articular prolotherapy with dextrose 12%and lidocaine2% 5 cc in the ankle 1 month apart it is performed and the patients studied by two TSK questionnaires and cumberlands . they are followed at intervals of zero, 1 nd 3 months after the start of treatment .

Main outcome variables

pain and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039323N2**

Registration date: **2020-10-11, 1399/07/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-11, 1399/07/20**

Update count: **0**

Registration date

2020-10-11, 1399/07/20

Registrant information

Name

Zahra Rezasoltani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4382 3476

Email address

z.rezasoltani@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-01, 1399/07/10

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison efficacy of extra articular dextrose prolotherapy with Routine physiotherapy in chronic ankle tendinopathy

Public title

extra articular dextrose prolotherapy and physiotherapy in ankle tendinopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

20<age<50 MRI evidence of tendinopathy conscious patient satisfaction symptoms more than 6 month

Exclusion criteria:

rheumatological disease diabetes localized local infection allergy to the drug to be injected use of anticoagulants INR disrupted immunodeficiency acute fracture

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocating of two groups with the same size of 20 participants (40 patients in total) we used block randomization with different block sizes. The sizes of blocks would be a multiple of 2 and a divisor of 40 (2,4,8). At first, the block sizes were selected randomly. Then, for each block, different permutations for equal group size were determined. Finally, one of the permutations was selected randomly. Random numbers were generated in an independent statistical office using Random allocation software.

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 Aja university of medical science

Street address

Etemadzade Ave.fatemi Ave, 501 hospital

City

Tehran

Province

Tehran

Postal code

1463773644

Approval date

2020-09-28, 1399/07/07

Ethics committee reference number

IR.AJAUMS.REC.1399.119

Health conditions studied**1****Description of health condition studied**

Ankle Tendinopathy

ICD-10 code

S90.91

ICD-10 code description

Unspecified superficial injury of ankle

Primary outcomes**1****Description**

Evaluation of pain intensity

Timepoint

Eyaluation of pain intensity befor ,1 and 3 month after injection or physiotherapy

Method of measurement

Cumperland outcome score questionnaire

2**Description**

Functional improvement

Timepoint

Evaluation of functional improvment befor ,1 and 3 month after injection or physiotherapy

Method of measurement

Cumperland outcome score questionnaire

3**Description**

Kinesiophobia

Timepoint

Befor ,1 and 3 month after injection or physiotherapy

Method of measurement

Tampa Scale for Kinesiophobia

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Physiotherapy treatment study group that include 10 sessions of treatment with Hotpack,Ultrasound,TENS in the affected area is performed

Category

Treatment - Devices

2**Description**

Intervention group: 2 injections of extra articular

prolotherapy with dextrose 12%and lidocaine2% 5 cc in the ankle 1 month apart it is performed

Category

Treatment - Drugs

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

501Hospital

Full name of responsible person

Sanaz Hamidipanah

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501 Hospital, Etemadzade Ave, Fatemi Blv, Tehran Town

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1411718546

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Y.hamidihamidi@yahoo.com

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

Artesh University of Medical Sciences

Full name of responsible person

Mostafa Shahrezaei

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Army 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**

Artesh University of Medical Sciences

Full name of responsible person

Sanaz Hamidipanah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available