

# 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)

###### Phone

+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

**Street address**

501 Hospital, Etemadzade Ave, Fatemi Blv, Tehran Town

**City**

Tehran

**Province**

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**Postal code**

1411718546

**Phone**

+98 21 4421 6034

**Email**

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

**Street address**

501 Hospital, Etemadzade Ave, Fatemi street, Tehran town

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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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## Person responsible for updating data

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### Contact

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**Email**

## 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