

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparsion between Therapeutic Effects of Intra-articular Botulinum Neurotoxin , Hyaluronic Acid, Prolotherapy with Dextrose and Physical Therapy in Knee Osteoarthritis

Protocol summary

Study aim

Comparison between Therapeutic Effects of Intra-articular Botulinum Neurotoxin , Hyaluronic Acid, Prolotherapy with Dextrose and physical therapy in Knee Osteoarthritis

Design

Clinical trial with control group,parallel group trial with single blinded outcome assessment, Randomised

Settings and conduct

The clinical trial is done at Tehran-Imam Reza Hospital,120 patients with Knee Osteoarthritis are randomly divided into groups of intervention (intra-articular injection of Botulinum Neurotoxin, Hyaluronic Acid, Prolotherapy with Dextrose at Knee) and control (physical therapy).Outcome assessments based on the Visual Analogue Scale are performed before the intervention, one month and three months later.The study is single blind and result's evaluator is kept blind.

Participants/Inclusion and exclusion criteria

Including criteria: Patients with knee osteoarthritis based on American College of Rheumatology criteria; Exclusion criteria: People with any rheumatologic, internal or neuromuscular disease that affects the knee joint,Patients with history of intra-articular injection or knee surgery or Patients who have contraindications for intra-articular injection.

Intervention groups

Intervention groups: Intra-articular injection of Botulinum Neurotoxin, Hyaluronic Acid, Prolotherapy with Dextrose at Knee Control group: Physical therapy for Knee Osteoarthritis

Main outcome variables

Pain Severity based on Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181217042028N2**

Registration date: **2019-04-18, 1398/01/29**

Registration timing: **retrospective**

Last update: **2019-04-18, 1398/01/29**

Update count: **0**

Registration date

2019-04-18, 1398/01/29

Registrant information

Name

Fatemeh Abdorrazaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6652 1827

Email address

rezasoltani@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparsion between Therapeutic Effects of Intra-

articular Botulinum Neurotoxin , Hyaluronic Acid,
Prolotherapy with Dextrose and Physical Therapy in Knee
Osteoarthritis

Public title

The Comparision between Therapeutic Effects of Intra-articular Botulinum Neurotoxin , Hyaluronic Acid, Prolotherapy with Dextrose and Physical Therapy in Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age older than 50 Crepitus or morning stiffness for less than 30 minutes Radiographic finding Symptoms longer than 3 monthes

Exclusion criteria:

Patient dissatisfaction The presence of other knee joint diseases History of surgery in the desired joint History of fracture in knee bones Intra-articular corticosteroid injection in the last 2 weeks Contraindication of intra-articular injection Immunodeficiency Sensitivity to botulinum toxin Dysfunction of the lower extremity due to neurological or internal medicine

Age

From **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with Knee Osteoarthritis will be recruited from the waiting list of an outpatient Department of Physical Medicine and Rehabilitation at Imam Reza Hospital. The Hospital is a large referral subspecialty center in Tehran affiliated with Artesh University of Medical Sciences. We are going to use block randomization with variable block size to provide four samples of equal size. Random numbers will be generated with a computer in an independent statistical office.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participant will be informed of his treatment, benefits and disadvantages, then consciously and satisfied be entered the study. The researcher also knows the type of treatment. The person who evaluates the outcome and the analyzer do not have any information on the type of treatment and are kept Blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Artesh University of Medical sciences

Street address

Artesh medical university, Etemad zade Ave, West Fatemi Ave

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2018-06-03, 1397/03/13

Ethics committee reference number

IR.AJAUMS.REC.1397.012

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Unilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Pain Severity based on Visual Analogue Scale

Timepoint

Before intervention, one and three months later

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

First Intervention group: Intra-articular injection of Botulinum Toxin at the knee

Category

Treatment - Drugs

2

Description

Second Intervention group: Intra-articular injection of Hyaluronic Acid at the knee

Category

Treatment - Drugs

3

Description

Third Intervention group: Intra-articular Prolotherapy with Dextrose at the knee

Category

Treatment - Drugs

4

Description

Control group: Physical Therapy for Knee Osteoarthritis

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Zahra Rezasoltani

Street address

Emam Reza hospital, Etemad zade Ave, West Fatemi Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mostafa Shahrezai

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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

Artesh 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

Fatemeh Abdorrazaghi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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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