Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Comparsion 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 intera-articular injection Immunodeficeincy 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
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
z.rezasoltani@ajaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mostafa Shahrezai
Street address
Artesh medical university, Etemad zade Ave, West Fatemi Ave
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
z.rezasoltani@ajaums.ac.ir
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
Street address
Emam reza hospital, Etemadzade St, West Fatemi St
City
Tehran
Province
Tehran
Postal code
1411718541
Phone
+98 21 6652 1827
Fax
Email
z.rezasoltani@ajaums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

Contact

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Artesh University of Medical Sciences

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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