Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Evaluation of Effects of Intra-articular Botulinum Neurotoxin on Pain and Function in Patients with Knee Osteoarthritis

Protocol summary

Study aim
The Evaluation of Effects of Intra-articular Botulinum Neurotoxin in Knee Osteoarthritis
Design
An intervention without a control group
Settings and conduct
For each knee, injection of 250 units of botulinum toxin (Dysport) in 501 hospital
Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age > 50 2. Crepitation or morning stiffness < 30 min 3. Radiographic presentation 4. Clinical symptom >3 months Exclusion criteria: 1. Patient dissatisfaction 2.Other articular disease in knee joint(RA, Gout, MG, LEMS, ALS) 3.surgical or fracture history in the joint 4. Corticosteroid knee injection in the last 2 weeks, hyalorunic acid injection or prolotherapy over the past year 5.Any intraarticular injection contraindication
Intervention groups
For each knee, we injected 250 units of botulinum toxin (Dysposort) diluted with 5 cc normal saline.Patients will be evaluated based on KOOS, VAS questionnaires. Variables are evaluated before treatment and one month after the end of treatment.
Main outcome variables
Pain; symptoms(stiffness, range of motion); activity of daily living(sitting and standing, upstairs, walking); quality of life

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180416039323N1**
Registration date: **2018-07-29, 1397/05/07**
Registration timing: **retrospective**

Last update: **2018-07-29, 1397/05/07**
Update count: **0**
Registration date
2018-07-29, 1397/05/07

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-30, 1397/02/10
Expected recruitment end date
2018-05-21, 1397/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Evaluation of Effects of Intra-articular Botulinum Neurotoxin on Pain and Function in Patients with Knee Osteoarthritis

Public title
Intra-articular Botulinum Neurotoxin in Knee Osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

age ⩾50 crepitation or morning stiffness < 30 min radiographic presentation clinical symptom > 3 months
Exclusion criteria:
Patient dissatisfaction Other articular disease in knee joint Surgical history in the joint Fracture history in bones of knee Corticosteroid knee injection in the last 2 weeks, hyalorunic acid injection or prolotherapy over the past year Any intraarticular injection contraindication Allergy to toxin Severe knee joint effusion

Age
From **50 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **23**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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
501 Hospital, Etemadzadeh street, Fatemi street, TehranTown

City
Tehran

Province
Tehran

Postal code
1411718546

Approval date
2018-04-30, 1397/02/10

Ethics committee reference number
IR.AJAUMS.REC.1397.001

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M19.2

ICD-10 code description
Secondary osteoarthritis of other joints

Primary outcomes

1

Description
evaluation of pain intensity and functional improvement with Knee Injury and Osteoarthritis Outcome Score questionnaire

Timepoint
evaluation of pain intensity and functional improvement before and 1 month after botulinum toxin injection

Method of measurement
Knee Injury and Osteoarthritis Outcome Score questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Injection of 250 units of botulinum toxin (Dysport), diluted in 5 ml of normal saline, in each knee

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
501 hospital

Full name of responsible person
Mahsa Khademi

Street address
501 Hospital, Etemadzadeh Street, Fatemi Street

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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?
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
Mahsa Khademi
Position
Resident
Latest degree
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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