

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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, hyaluronic 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

###### Name

Zahra Rezasoltani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 4382 3476

###### Email address

z.rezasoltani@ajajums.ac.ir

##### 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  $\geq$ 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,  
hyaluronic 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

**City**

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**Province**

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**Postal code**

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**Phone**

+98 21 8802 8350

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m\_khademii@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, Etemadzadeh Street, Fatemi Street

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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**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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Resident

**Latest degree**

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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