

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

An Investigation into the Efficacy of Intra-articular Injection of Botulinum Toxin versus Steroid on Pain and Function of Patients with Knee Osteoarthritis

Protocol summary

Summary

Objectives: The aim of this study is to compare efficacy and safety of intra articular injection of Botulinum toxin versus steroid (triamcinolon acetonide) in patients with knee OA. **Study Design:** Double blind Randomized controlled clinical trial. **Setting and Conduct:** In this study a total of 40 patients with more than three months of chronic pain in the knee joints along with consistent imaging findings (Kellgren-Lawrence score of II&III) would be enrolled and randomly allocated into two groups of Botulinum toxin and steroid. **Participants:** Patients suffering from mild to moderate knee OA referred to Shahid Modarres Hospital of Saadat Abad in Tehran in 2016. **Interventions:** a single injection of Botulinum toxin, Dysport® (half of a 500-IU vial) in one group and a single vial of 40 mg/ml triamcinolone acetonide in other group. **Outcome measuers:** Patients would be evaluated at baseline and 8 & 24 weeks after injection for pain, stiffness and function using the Visual Analog Scale (VAS) and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017103013442N20**
Registration date: **2017-11-12, 1396/08/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-12, 1396/08/21

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

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Recruitment status

Recruitment complete

Funding source

Physical Medicine and Rehabilitation Department of Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An Investigation into the Efficacy of Intra-articular Injection of Botulinum Toxin versus Steroid on Pain and Function of Patients with Knee Osteoarthritis

Public title

An Investigation into the Efficacy of Intra-articular Injection of Botulinum Toxin versus Steroid on Pain and Function of Patients with Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion critetia: Confirmed knee-osteoarthritis patients

based on American College of Rheumatology (ACR) criteria with ages ranging from 40 to 75 years; more than 3 months symptoms resistant despite the conservative treatment; grade 2 or 3 according to KLS system in plain x-ray film. Exclusion criteria: Infection and active wound in knee; Gout or psudogout; neuromuscular illnesses; Pregnancy or breast-feeding; any history of intra articular injection over the past 3 months; Acute trauma of knee; Recent physiotherapy during last 3 months; Genuvarum or valgum more than 20 degrees; Radioculophathy; BMI $\geq$ 35; Hx of allergy to Botulinium Toxin; Systemic illnesses like diabetes melitus, immunodeficiency, and vascular collagen diseaes; prior history of cancer or active malignant lesions; ages below 40 years or above 75 years.

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences,
Sahahid Arabi street, Yaman street, Shahid Chamran Highway

City

Tehran

Postal code

Approval date

2017-05-16, 1396/02/26

Ethics committee reference number

IR.SBMU.MSP.REC.1396.113

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description

Knee Pain

Timepoint

Before intervention and 8 & 24 weeks after injection

Method of measurement

WOMAC questionnaire

Secondary outcomes

1

Description

Pain

Timepoint

Before intervention and 8 & 24 weeks after injection

Method of measurement

VAS questionnaire

2

Description

Joint Stiffness

Timepoint

Before intervention and 8 & 24 weeks after injection

Method of measurement

WOMAC questionnaire

3

Description

Patient Function

Timepoint

Before intervention and 8 & 24 weeks after injection

Method of measurement

WOMAC questionnaire

Intervention groups

1

Description

Intervention group 1: Botulinium toxin, knee intraarticular injection, half of 500-IU vial, a single injection

Category

Treatment - Drugs

2

Description

Intervention group 2: Triamcinolone acetonide, knee intraarticular injection, 1cc of 40mg/ml vial, a single injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Ehsan Enayati

Street address

Shahid Modarres Hospital, Kaj square, Saadat Abad street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Physical Medicine and Rehabilitation Department of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Seyed Ahmad Raeissadat

Street address

Physical Medicine and Rehabilitation Department, Shahid Modarres Hospital, Kaj square, Saadat abad

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Physical Medicine and Rehabilitation Department of Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Physical Medicine and Rehabilitation Department, Shahid Beheshti University of Medical Sciences, Sch

Full name of responsible person

Ehsan Enayati

Position

Resident in PM&R

Other areas of specialty/work

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Full name of responsible person

Seyed Ahmad Raeissadat

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Shahid Modarres Hospital

Full name of responsible person

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Position

Associate Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty