Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

An Investigation into the Efficacy of Intra-articular Injection of Botulinium 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 Botulinium 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 Botulinium toxin and steroid. Participants: Patients suffering from mild to moderate knee OA refered to Shahid Modarres Hospital of Saadat Abad in Tehran in 2016. Interventions: a single injection of Botulinium 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

a_raeissadat@sbmu.ac.ir

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 Botulinium Toxin versus Steroid on Pain and Function of Patients with Knee Osteoarthritis

Public title

An Investigation into the Efficacy of Intra-articular Injection of Botulinium 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≥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 intraarticuar injection, half of 500-IU vial, a single injection

Category
Treatment - Drugs

2

Description
Intervention group 2: Triamcinolone acetonide, knee intraarticuar 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

City
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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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Seyed Ahmad Raeissadat

Position
Associate Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Modarres Hospital

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Seyed Ahmad Raeissadat

Position
Associate Professor

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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