Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

comparison of the safety and efficacy of botulinum toxin A injection combined with corticosteroids with corticosteroids with palcebo in the treatment of patients with supraspinatus tendinopathy

Protocol summary

Study aim
Evaluation and comparison of the safety and efficacy of botulinum toxin A injection with corticosteroids and corticosteroids with placebo in the treatment of patients with supraspinatus tendinopathy

Design
A controlled clinical trial with parallel groups, double-blind, randomized, on 20 patients. Random allocation software will be used for randomization.

Settings and conduct
Study location: Shohada Tajrish Hospital, Shahid Beheshti University of Medical Sciences, Tehran; Study population: Patients with shoulder pain and limited range of motion diagnosed with supraspinatus tendinopathy; Type of blinding: Double-blind; Method of blinding: Failure to inform the patient and therapist about the contents of the injection syringe, which are identical in color and appearance

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 20 to 70 years; confirmation of symptoms of supraspinatus tendinopathy in clinical examination and ultrasound. Exclusion criteria: History of trauma to the hand and shoulder area; complete supraspinatus tear; pregnancy and lactation; history of sensitivity to corticosteroids and botulinum toxin; concomitant frozen shoulder disease

Intervention groups
Intervention group: Patients with supraspinatus tendinopathy who receive corticosteroid and botulinum toxin injections as first line treatment. Control group: Supraspinatus tendinopathy patients who receive corticosteroid injections and placebo as first-line treatment.

Main outcome variables
Pain intensity, range of motion, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240729062578N2**
Registration date: **2026-01-27, 1404/11/07**
Registration timing: **prospective**

Last update: **2026-01-27, 1404/11/07**
Update count: **0**

Registration date
2026-01-27, 1404/11/07

Registrant information

Name
Mahboobe Ghanbarian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2222 4450

Email address
mahboobeghanbarian313@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-02-24, 1404/12/05

Expected recruitment end date
2026-03-21, 1405/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
comparison of the safety and efficacy of botulinum toxin A injection combined with corticosteroids with corticosteroids with palcebo in the treatment of patients with supraspinatus tendinopathy

Public title
Safety and effectiveness of Botox injections combined with cortisone in shoulder tendon problems

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with supraspinatus tendinopathy Confirmation of the problem by examination and ultrasound Not having previously received treatment Intervention should be carried out as a first line Age between 20-70 years

Exclusion criteria:
History of trauma to the hand and shoulder area in the last 6 months History of humerus fracture Complete rupture of the supraspinatus tendon Acromioclavicular joint osteoarthritis Calcific tendonitis Pregnancy and breastfeeding Presence of nerve damage or neurological disorders that cause upper limb dysfunction The existence of psychological problems History of shoulder surgery Patient's lack of cooperation in assessing range of motion History of corticosteroid injection into the shoulder within the past 6 months Concomitant radiculopathy Coincidence with frozen shoulder Systemic inflammatory diseases History of sensitivity to botulonium toxin History of sensitivity to corticosteroid

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 20 patients with supraspinatus tendinopathy will be enrolled in a simple randomization study. To randomly assign individuals to the study groups (intervention group and comparison group), a block randomization method will be used. In this method, blocks of 2 (including one person in the intervention group and one person in the comparison group) will be used in a 1:1 ratio. Random Allocation software will be used to generate random sequences. Individuals will be divided into two intervention groups (10 people) and a control group (10 people). In the intervention group, 30 units of botulinum toxin A along with 40 units of steroid will be injected into the tendon sheath of the supraspinatus muscle. In the control group (placebo), 30 units of normal saline will be injected into the supraspinatus muscle and 40 units of steroid will be injected into the tendon sheath of the supraspinatus muscle. The injecting physician will not know about the substance injected into the muscle. Patients are also aware of the study conditions before the study, but during the study they do not know which group they are in and whether they will receive botulinum toxin in addition to the corticosteroid.

Blinding (investigator's opinion)
Double blinded

Blinding description
Because there is no difference in volume, color, or appearance between normal saline and botulinum toxin, there is no need to cover the syringe Information about the contents of the syringe is not given to the patient or therapist.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Koodakya Alley, Arabi Ave, Daneshjoo Blvd, Velenjak

City
Tehran

Province
Tehran

Postal code
1983969411

Approval date
2025-10-23, 1404/08/01

Ethics committee reference number
IR.SBMU.RETECH.REC .1404.163

Health conditions studied

1

Description of health condition studied
Supraspinatus tendinopathy

ICD-10 code
M75.9

ICD-10 code description
Shoulder lesion, unspecified

Primary outcomes

1

Description

Shoulder range of motion

Timepoint

Before injection,1and 3 months later

Method of measurement

Physical exam and questioner

2

Description

Shoulder pain

Timepoint

Before injection,1and 3 months later

Method of measurement

Questioner

Secondary outcomes

1

Description

Quality of life

Timepoint

Before injection,1and 3months later

Method of measurement

Questioner

Intervention groups

1

Description

Intervention group: One injection of 30 units of Dysport into the supraspinatus muscle and 40 mg of methylprednisolone into the bursa of the supraspinatus tendon sheath once

Category

Treatment - Drugs

2

Description

Control group: one injection of 40 mg of methylprednisolone into the bursa of the supraspinatus tendon sheath and 30 units of normal saline into the supraspinatus muscle once

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish hospital

Full name of responsible person

Seyed Mansoor Raygani ,MD

Street address

Darband Alley, Shahrdari Street

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2222 3355

Email

mahboobeghanbarian313@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Darband Alley, Shahrdari Street

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2352 3710

Email

mahboobeghanbarian313@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Mansoor raygani

Position

Director of the Department of Physical Medicine and Rehabilitation, Shahid Beheshti University of Me

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address
Darband Alley, Shahrdari Street
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2352 3710
Email
mahboobeghanbarian313@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Mansoor raygani
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Shohadaye Tajrish Hospital, Darband Avenue, Shahrdari Street
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2352 3710
Fax
+98 21 2352 3711
Email
mahboobeghanbarian313@gmail.com
Web page address
https://sbmu.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahboobe Ghanbarian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Darband Alley, Shahrdari Street
City
Tehran
Province
Tehran
Postal code
قبلی
Phone
قبلی
Email
mahboobeghanbarian313@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Patients are unwilling to disclose their information.
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