

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the efficacy of corticosteroid injection with and without ultrasound-guided in paraplegic spinal cord injury patients, below T6 neurologic level with rotator cuff tendinopathy in shoulder pain and function improvement.

Protocol summary

Study aim

Comparison of the efficacy of corticosteroid injection with and without ultrasound-guided in subacromial bursa in paraplegic spinal cord injury patients with rotator cuff tendinopathy in shoulder pain and function improvement.

Design

Two arm parallel group, randomised clinical trial with 15 patients in which group, blinded patient and outcome assessment.

Settings and conduct

Physical medicine & rehabilitation clinic in Tehran medical university 4 Block randomization method

Participants/Inclusion and exclusion criteria

Inclusion criteria: Paraplegic spinal cord injury patients below T6 neurologic level with rotator cuff tendinopathy Age between 20 to 60 years Shoulder pain & positive Neer test & Hawkins-Kennedy test VAS>4 Exclusion criteria: History of stroke, head trauma, rheumatoid arthritis, glenohumeral osteoarthritis, humeral or clavicle fracture, diabetes mellitus, infection, tumor, pregnancy, steroid sensitivity, coagulopathy subacromial injection over 8 weeks ago

Intervention groups

Patients divided in two groups: A & B. A: Control (subacromial anatomical landmark injection)
B: Intervention (subacromial Ultrasound guided injection)

Main outcome variables

Selection of the choice method in corticosteroid injection in rotator cuff tendinopathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180928041163N1**

Registration date: **2018-11-07, 1397/08/16**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-07, 1397/08/16**

Update count: **0**

Registration date

2018-11-07, 1397/08/16

Registrant information

Name

Najmeh Bolandnazar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2110

Email address

n-bolandnazar@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of corticosteroid injection with and without ultrasound-guided in paraplegic spinal cord

injury patients, below T6 neurologic level with rotator cuff tendinopathy in shoulder pain and function improvement.

Public title

The efficacy of sonography in corticosteroid injection in subacromial bursa in rotator cuff tendinopathy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Paraplegic spinal cord injury patients below T6 neurologic level with rotator cuff tendinopathy Age between 20 to 60 years Shoulder pain & positive Neer test & Hawkins-Kennedy test VAS>4

Exclusion criteria:

History of stroke, head trauma, rheumatoid arthritis, glenohumeral osteoarthritis, humeral or clavicle fracture, diabetes mellitus, infection, tumor, pregnancy, steroid sensitivity, coagulopathy _subacromial injection over 8 weeks ago

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

Both shoulders or just right shoulder or just left shoulder.

Randomization (investigator's opinion)

Randomized

Randomization description

4 block randomization with sealed paper

Blinding (investigator's opinion)

Single blinded

Blinding description

At the first we explain for all participants that in this study, corticosteroid injected in subacromial bursa and this treatment helps to all of them but in the one group with and the other group without ultrasonography and partitheners just don't know that stay in which group. partitheners according to four block randomization list stay in with & without sonography group and received ID. Chief researcher (Physiatrist), data collector, outcome evaluator oriented about ID content (with or without sonography), so the trial is single blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2018-01-03, 1396/10/13

Ethics committee reference number

IR.TUMS.IKHC.REC.1396.4129

Health conditions studied

1

Description of health condition studied

Rotator cuff tendinopathy

ICD-10 code

M20-M25

ICD-10 code description

Other joint disorders

Primary outcomes

1

Description

Shoulder pain

Timepoint

Before intervention, after 2 weeks, after 2 months

Method of measurement

Visual Analogue Scale

2

Description

Shoulder function

Timepoint

Before intervention, after 2 weeks, after 2 months

Method of measurement

Constant score

Secondary outcomes

1

Description

Quality of life

Timepoint

Before intervention, after 2 weeks, after 2 months

Method of measurement

Intervention groups

1

Description

Intervention group: 1cc depomedrol (Belgium) with 2 cc
lidocain ultrasound guided injection in subacromial bursa

Category

Treatment - Devices

2

Description

Control group: 1cc depomedrol (Belgium) with 2 cc
lidocain blind injection in subacromial bursa

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Najmeh Sadat Boland Nazar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Reza Malekzadeh

Street address

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nchrd2017@bums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Najmeh Bolandnazar

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Najmeh Bolandnazar

Position

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Other areas of specialty/work

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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

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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