

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 participants just do not know that stay in which group. Participants 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

##### Street address

Keshavarz Blvd, Imam Khomeini Hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 6119 2110

##### Email

n-bolandnazar@razi.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Reza Malekzadeh

##### Street address

Keshavarz Blvd, Imam Khomeini Hospital

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

##### Phone

+98 21 6119 2110

#### Email

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

##### Street address

Imam Khomeini hospital, Keshavarz Blvd

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+98 21 6119 2110

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n-bolandnazar@razi.tums.ac.ir

## Person responsible for scientific inquiries

#### Contact

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Tehran University of Medical Sciences

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**Person responsible for updating data****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

**Street address**

Imam Khomeini hospital, Keshavarz Blvd

**City**

Tehran

**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