Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Comparision 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 devided in two groups:A & B. A:Control (subacromial anatomical landmarc 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)

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+98 21 6119 2110

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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,corticostroid injected in subacromial bursa and this treatment helps to all of them but in the one group with and the other group without ultrasonograghy and partitheners just don not know that stay in wich group. partisheners according to four block randomization list stay in with & without sonography group and recived ID. Cheif researcher(Physiatrist) ,data collector,outcome evaluator oriented about ID content(with or without sonography), so the traial 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
Rotatorcuff 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

World Health Organization Quality of Life BREF Questionair

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
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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
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Keshavarz Blvd,Imam Khomeini Hospital
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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 updating data

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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