Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Three different methods in pain management and treatment of patients with idiopathic frozen shoulder: supracondylar nerve block (SSNB) together with physiotherapy, intra-articular injection of corticosteroid together with physiotherapy and isolated physiotherapy.

Protocol summary

Study aim
Three different methods in pain management and treatment of patients with idiopathic frozen shoulder: supracondylar nerve block (SSNB) together with physiotherapy, intra-articular injection of corticosteroid together with physiotherapy and isolated physiotherapy.

Design
Randomized clinical trial, with parallel groups, without blinding.

Settings and conduct
non-blinded randomized clinical trial

Participants/Inclusion and exclusion criteria
inclusion criteria: pain at rest and limited ROM for at least 3 months. failure in oral medical therapy for at least 3 months normal finding in shoulder imaging limited forward flexion<100degree, limited external rotation<50%, limited internal rotation. Exclusion criteria: Evidence of degenerative changes in the shoulder joint and rotator cuff tear. History of previous shoulder surgery, trauma, or drug allergy. History of intra-articular shoulder joint injection.

Intervention groups
Intervention group1: Physiotherapy group Intervention group2: IACI (Intra articular corticosteroid injection)+ Physiotherapy Intervention group3: SSNB (Supra scapular nerve block)+ Physiotherapy

Main outcome variables
Range of motion SPADI (The shoulder pain and disability index)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110809007274N16**
Registration date: **2018-08-03, 1397/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-03, 1397/05/12**
Update count: **0**

Registration date
2018-08-03, 1397/05/12

Registrant information

Name
Mohsen Mardani Kivi

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 13 1321 1470

Email address
mardani@gums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-05, 1397/03/15

Expected recruitment end date
2018-09-06, 1397/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Three different methods in pain management and treatment of patients with idiopathic frozen shoulder:

supracondylar nerve block (SSNB) together with physiotherapy, intra-articular injection of corticosteroid together with physiotherapy and isolated physiotherapy.

Public title
Three different methods in pain management of patients with frozen shoulder: nerve block plus physical therapy, intra-articular corton injection plus physical therapy and isolated physical therapy.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
pain at rest and limited range of motion for at least 3 months duration (stage i & II in Kisner & Colby classification) . failure in oral medical therapy for at least 3 months normal finding in shoulder imaging limited forward flexion<100degree, limited external rotation<50%, limited internal rotation

Exclusion criteria:
Evidence of degenerative changes in the shoulder joint (Glenohumeral arthritis) and rotator cuff tear History of previous shoulder surgery, trauma, or drug allergy History of intra-articular or peri-articular shoulder joint injection

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
block randomization

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee, Guilan University of Medical Sciences

Street address
Research vice-chancellor of Guilan university of medical sciences building, Shahid Beheshti blv.

City
Rasht

Province
Guilan

Postal code
4193834881

Approval date
2018-05-19, 1397/02/29

Ethics committee reference number
IR.GUMS.REC.1397.046

Health conditions studied

1

Description of health condition studied
Adhesive capsulitis of shoulder

ICD-10 code
M75.0

ICD-10 code description
Adhesive capsulitis of shoulder

Primary outcomes

1

Description
Range of motion

Timepoint
pre-treatment, 2nd, 4th, 6th and 12th weeks post treatment

Method of measurement
Goniometer

Secondary outcomes

1

Description
Measuring pain and disability of the patient from 0 to 100

Timepoint
pre-treatment, 2nd, 4th, 6th and 12th weeks post treatment

Method of measurement
SPADI (The shoulder pain and disability index)

Intervention groups

1

Description
Intervention group1: Physiotherapy group in which all case will receive the PT protocol.

Category
Treatment - Other

2

Description

Intervention group2: IACI (Intra articular corticosteroid injection)+ Physiotherapy: all patient will receive IACI (including 8ml of Lidocaine plus 80mg of Prednisolone Acetate). for all patient in this group the PT protocol will be performed.

Category

Treatment - Drugs

3

Description

Intervention group3: SSNB (Supra scapular nerve block)+ Physiotherapy: all patient will receive SSNB (including 8ml of Lidocaine 1% plus 80mg of Prednisolone Acetate) under the sonography guide. for all patient in this group the PT protocol will be performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Poursina Hospital

Full name of responsible person

Mohsen Mardani Kivi MD.

Street address

poursina Crossroads, Poursina hospital

City

Rasht

Province

Guilan

Postal code

4137816357

Phone

+98 13 3331 1178

Email

mardani.kivi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati MD, Research chancellor of Guilan university of medical science

Street address

Research vice-chancellor of Guilan university of medical sciences building, Shahid Beheshti blv.

City

Rasht

Province

Guilan

Postal code

4193834881

Phone

+98 13 3331 1178

Email

mardani@gums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research, Guilan 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

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohsen Mardani Kivi

Position

Orthopedic Surgeon, Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Orthopedic Department, Poursina Hospital, Parastar avenue

City

Rasht

Province

Guilan

Postal code

4137816357

Phone

+98 13 3331 1178

Fax

Email

mardani@gums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohsen Mardani Kivi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Orthopedic Department, Poursina Hospital, Parastar avenue.

City

Rasht

Province

Guilan

Postal code

4137816357

Phone

+98 13 3331 1178

Fax

Email

mardani@gums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohsen Mardani Kivi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Orthopedic Department, Poursina Hospital, Parastar avenue.

City

Rasht

Province

Guilan

Postal code

4137816357

Phone

+98 13 1321 1470

Fax

Email

mardani@gums.ac.ir

Web page address

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

Not applicable.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available