

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Assessing Short-term Effects of Subacromial Injection with Ketorolac and Methylprednisolone in Rotator Cuff Injury Patients

Protocol summary

Study aim

Comparison of the short-term effects of subacromial injection of methylprednisolone with ketorolac in improving shoulder movements, reducing pain and improving performance in patients with impingement syndrome referred to Imam Khomeini Hospital Complex (IKHC) in Tehran in 2023

Design

In this study, patients are divided into two groups after being admitted to the clinic and undergoing paraclinical examinations and confirming the diagnosis of impingement syndrome. A group is prepared for subacromial injection of methylprednisolone and a group for subacromial injection of ketorolac.

Settings and conduct

Patient's demographic information (age, sex, history of previous illness or surgery, drug use, duration of pain onset and limitation of movement, and its possible cause) are recorded. The amount of ROM under study and the amount of limitation of ROM are recorded based on the Oxford questionnaire. Shoulder injection is performed in the operating room and the patient is discharged. After 3-month follow up, the aforementioned questionnaire is completed by returning. The answers are recorded and subjected to statistical analysis.

Participants/Inclusion and exclusion criteria

Patients with impingement syndrome with shoulder pain and limitation of active shoulder movements. Age above 18 years

Intervention groups

Patient with shoulder impingement syndrome

Main outcome variables

Steroid injection is one of the non-surgical treatments for SIS. However, the process is yet unknown. Despite anti-inflammatory effects of these drugs, their potential side effect limits the application of this method over time. In this study, we aim to compare effects of ketorolac with regards to its fewer complication reports in SIS patients with Depomedrol.

General information

Reason for update

Acronym

SASI

IRCT registration information

IRCT registration number: **IRCT20230625058584N1**

Registration date: **2023-07-03, 1402/04/12**

Registration timing: **prospective**

Last update: **2023-07-03, 1402/04/12**

Update count: **0**

Registration date

2023-07-03, 1402/04/12

Registrant information

Name

reza omid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7704 1848

Email address

dr_rezaomid66@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2023-09-01, 1402/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing Short-term Effects of Subacromial Injection with Ketorolac and Methylprednisolone in Rotator Cuff Injury Patients

Public title

comparison of short-term effects of subacromial injection of ketorolac and steroids in rotator cuff muscle injury

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed with Shoulder Impingement Syndrome (SIS) and shoulder pain and reduced range of motion of affected shoulder Older than 18 years

Exclusion criteria:

Patients diagnosed with frozen shoulder Other pathologies associated with shoulder pain Rotator cuff tearing Shoulder and scapular fracture

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

In this research, patients with impingement syndrome are categorized into two groups following their admission to the clinic and undergoing paraclinical evaluations to confirm their diagnosis. One group is prepared for subacromial injection of methylprednisolone, while the other receives subacromial injection of ketorolac. At the scheduled time, patients visit the operating room as outpatients, where the injection is administered to them.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Tehran University of Medical Science

Street address

Imam Khomeini Hospital Complex- Tehran University of Medical Science

City

Tehran

Province

Tehran

Postal code**Approval date**

2018-04-22, 1397/02/02

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.315

Health conditions studied**1****Description of health condition studied**

Subacromial Impingement Syndrome

ICD-10 code

M75.4

ICD-10 code description

Impingement Syndrome of Shoulder

Primary outcomes**1****Description**

Oxford Shoulder Score (OSS)

Timepoint

3 months

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Single subacromial injection of Depomedrol (methylprednisolone 40 mg/mL) mixed with 1 mL of Lidocaine Hydrochloride 2% (Sinadarou)

Category

Treatment - Drugs

2**Description**

Control group: single subacromial injection of Ketorolac Tromethamine (30mg/mL) mixed with 1 mL of Lidocaine Hydrochloride 2%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Reza Omid

Street address

Shariati Hospital, Jalal Street, Amir-Abad district,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Tehran Medical University of Sciences, Poursina
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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

Reza Omid

Position

Research Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected dedentified for IPD

When the data will become available and for how long

Access 1 month after result publication

To whom data/document is available

For academic institution members

Under which criteria data/document could be used

For further research not for any level of intervention

From where data/document is obtainable

From email address

What processes are involved for a request to access data/document

With shared research filed with academical prove

Comments