Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 impingment 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 Scinece

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

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Shariati Hospital, Jalal Street, Amir-Abad destrict, Tehran, Iran

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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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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