

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Evaluation of the Success rate of Shoulder Arthrocentesis & Injection methods by Orthopedic surgery residents With/without landmarks

#### Protocol summary

##### Study aim

Introducing a method with greater ease and success for orthopedic assistants to perform arthrocentesis and injection of the shoulder joint

##### Design

For randomization, 1:1:1:1:1 blocks will be used and no more than two people will be placed in any of the groups. The process of randomization will be done by a person outside the research, and the researcher and assistants participating in the research will not be aware of the process. The sample size includes 10 senior residents and 30 patients

##### Settings and conduct

A cross-over trial in 2024 in the orthopedic department of Imam Khomeini Hospital of Tehran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criterion for assistants: studying orthopedic residency course at Tehran University of Medical Sciences. Inclusion criteria for patients: those who referred to Imam Khomeini Hospital of Tehran University of Medical Sciences and are candidates for shoulder arthroscopy with clinical examination and imaging evaluations including X-ray, CT or MRI will be included in the study; age between 18 and 70 years; diagnosis requiring arthroscopic shoulder surgery. Exclusion criteria: Existence of anatomical abnormality in pre-surgical imaging; previous arthroscopy with the previous incision remaining

##### Intervention groups

Each assistant will perform a total of three shoulder arthrocentesis interventions on one patient, and the result will be checked with an arthroscope: Intervention 1: Arthrocentesis without drawing (anatomical)landmarks and without traction of the (patient's) hand; Intervention 2: Arthrocentesis with drawing landmarks and without traction of the hand; Intervention 3: Arthrocentesis with drawing landmarks and with traction of the hand

##### Main outcome variables

Ease and success of arthrocentesis and shoulder joint injection techniques by residents Orthopedics in two methods with and without landmarks

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230820059200N1**

Registration date: **2023-10-03, 1402/07/11**

Registration timing: **prospective**

Last update: **2023-10-03, 1402/07/11**

Update count: **0**

##### Registration date

2023-10-03, 1402/07/11

##### Registrant information

##### Name

Seyyedhosein Jahanbakhsh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7790 6248

##### Email address

dr.s.h.jahanbakhsh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-20, 1402/12/01

##### Expected recruitment end date

2024-09-20, 1403/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Evaluation of the Success rate of Shoulder Arthrocentesis & Injection methods by Orthopedic surgery residents With/without landmarks

**Public title**  
Shoulder arthrocentesis in two Methods with and without landmarks

**Purpose**  
Diagnostic

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
The patient's age is between 18 and 70 years old  
Diagnosis requiring arthroscopic surgery of the shoulder, such as rotator cuff tears, labrum repair, etc. Consent to participate in the study  
**Exclusion criteria:**  
Existence of anatomic abnormality in pre-surgery imaging  
Previous arthroscopy in which the previous incision has remained

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **10**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
This study will be conducted as a cross-over trial in 1402 in Imam Khomeini Hospital of Tehran University of Medical Sciences and in the orthopedic department of this hospital. The study design process will be based on CONSORT guidelines. Study participants will perform shoulder arthrocentesis a total of 3 times: 1 time without landmarks, 1 time with landmarks and without traction, and 1 time with landmarks and with traction. The order of interventions in individuals will be determined in a simple random manner. At first, the necessary training regarding the anatomy of the shoulder joint and how to perform shoulder arthrocentesis with and without landmarks and, in the case of landmarks, with and without traction, will be given to the assistants by the orthopedic professor. The procedure will be performed by the "senior" resident of the group. It will be done under the supervision of the relevant teacher. Then 10 participants in the study will be randomly assigned to one of the following 6 groups and a maximum of two people will be placed in each group. Group 1: without

landmark - with landmark with traction - with landmark without traction  
Group 2: without landmark - with landmark without traction - with landmark with traction  
Group 3: with landmark without traction - without landmark - with landmark with traction  
Group 4: with landmark without traction - with landmark with traction - without landmark  
Group 5: with landmark with traction - without landmark - with landmark without traction  
Group 6: with landmark with traction - with landmark without traction - without landmark  
For randomization, 1:1:1:1:1:1 blocks will be used and no more than two people will be placed in any of the groups. The process of randomization will be done by a person outside the research, and the researcher and assistants participating in the research will not be aware of the process. This is for Allocation Concealment, so that there is no intervention in terms of allocation of interventions by the research team.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The researchers and the statistical analyst will not be aware of the intervention and the interventions will be defined as A, B, and C by a person outside the research for the researchers and the team of researchers from the assigned order and also the definition of the codes until after the implementation. Research will not be informed. In this way, the study will be done in a double-blind manner

**Placebo**

Not used

**Assignment**

Crossover

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Research Ethics Committee of Imam Khomeini Hospital Complex - Tehran University of Medical Sciences

**Street address**

No 35, Barati avenue, Ayat avenue, Nobovat square, Narmak

**City**

Tehran

**Province**

Tehran

**Postal code**

1648819813

**Approval date**

2023-06-20, 1402/03/30

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1402.151

## Health conditions studied

### 1

#### Description of health condition studied

Evaluation of the success rate of shoulder arthrocentesis & injection methods by orthopedic surgery residents with/without landmarks

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Success rate of orthopedic assistants in performing shoulder arthrocentesis

#### Timepoint

The time period of the variable measurement is during the same day during the arthroscopic surgery

#### Method of measurement

After the complete arthrocentesis, the entry of the needle into the joint space will be evaluated by the arthroscope, and the assistant's performance will be graded from 0 to 2 by the professor:0 (not entering the shoulder joint)1 (entering the shoulder joint through the rotator cuff or biceps)2 (Entry through rotator interval)-In other words, the assistant's success in entering the Angiocath into the shoulder joint space will be checked with an arthroscope and scoring will be done as described above.

### 2

#### Description

Duration of arthrocentesis

#### Timepoint

The time period of the variable measurement is during the same day during the arthroscopic surgery

#### Method of measurement

At the same time as the landmark is drawn, the time is measured with a stopwatch and ends after the needle enters the skin, and the procedure time is measured in seconds.

### 3

#### Description

The ease of performing the procedure according to the assistant based on the Likert scale

#### Timepoint

The time period of the variable measurement is during the same day during the arthroscopic surgery

#### Method of measurement

The ease of performing the procedure is given a score by the resident who performed the procedure based on a Likert scale from 1 (least ease) to 10 (maximum ease).

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention :Insertion of the angiocath needle only once without drawing an anatomical landmark and in the condition that the hand is not in traction

#### Category

Early detection

### 2

#### Description

Second Intervention: assistant on the same patient as the first intervention; will perform the second intervention: the second intervention: entering only one time of the angiocath needle based on drawing the anatomical landmarks and while the patient's hand is not in traction

#### Category

Early detection

### 3

#### Description

Third Intervention: assistant on the same patient as the first intervention; He will perform the third intervention: The third intervention: the insertion of only one time of the angiocath needle based on the drawing of anatomical landmarks and while the patient's hand is in traction.

#### Category

Early detection

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam khomeini hospital complex

##### Full name of responsible person

Seyyed Hosein Jahanbakhsh

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No 35, Barati avenue, Ayat avenue, Nobovat square, Narmak

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##### Province

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##### Email

dr.s.h.jahanbakhsh@gmail.com

## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Nima Rezai

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Medical school, Poorsina Ave, qods Ave, Enghelab Ave, Tehran town

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deanmed@tums.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**

Seyyed Hosein Jahanbakhsh

**Position**

orthopaedic surgery resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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**Position**

Professor

**Latest degree**

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**Phone**

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**Person responsible for updating data**

**Contact**

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Tehran University of Medical Sciences

**Full name of responsible person**

Seyyed Hosein Jahanbakhsh

**Position**

orthopaedic surgery resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

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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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available