Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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, 1:1:1:1:1:1 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Seyyed Hosein Jahanbakhsh

Position
orthopaedic surgery resident

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

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Person responsible for updating data

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Full name of responsible person
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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