

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Efficacy of intra-articular shoulder injection verses combined supra scapular and axillary nerve block for adhesive capsulitis: A double-blind Randomized Control Trial

#### Protocol summary

##### Study aim

The purpose of this study was to compare the short- and long-term effects on the Shoulder Pain and Disability Index (SPADI) of axillary nerve block (ANB) and intra-articular injection (IAI) vs suprascapular nerve block (SSNB) guided by ultrasonography as well as to find out how they affect the patients' quality of life who have AC.

##### Design

A Randomized Control Trial (RCT) with two group interventions, each group have 40 participants.

##### Settings and conduct

Ghurki Trust Teaching Hospital, Lahore. Participants and data collector will be blinded.

##### Participants/Inclusion and exclusion criteria

6.1 Inclusion Criteria: • Stage 2-3 AC unilateral • No shoulder injuries in the previous three months • Absence of shoulder injections • Absence of bleeding disorders • no prior history of cancer • absence of inflammatory illness history • Ages Eligible for Study: 30 Years to 70 Years (Adult, Older Adult) • Sexes Eligible for Study: All  
6.2 Exclusion Criteria: • Malignancy • Inflammatory disease

##### Intervention groups

Participants will be randomly assigned to two treatment groups: suprascapular and axillary nerve blocks or intra-articular shoulder injection. The nerve block group receives ultrasound-guided blocks with a 10 mL solution of 40 mg Prednisolone, 0.125% bupivacaine, and 0.125% lidocaine. Group II receives an intra-articular injection into the glenohumeral joint, also guided by ultrasound, using a similar anesthetic and corticosteroid mix for pain relief.

##### Main outcome variables

Shoulder Pain and Disability Index (SPADI), Pain, Range of Motion ROM, assessing quality of life.

#### General information

##### Reason for update

##### Acronym

AC adhesive capsulitis supra scapular nerve block SSNB axillary nerve blockAND

##### IRCT registration information

IRCT registration number: **IRCT20240901062926N1**

Registration date: **2024-09-22, 1403/07/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2024-09-22, 1403/07/01**

Update count: **0**

##### Registration date

2024-09-22, 1403/07/01

##### Registrant information

##### Name

Muhammad Tayyeb

##### Name of organization / entity

Superior University

##### Country

Pakistan

##### Phone

+92 307 8625941

##### Email address

tayyabm851@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-09-05, 1403/06/15

##### Expected recruitment end date

2024-11-20, 1403/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The Efficacy of intra-articular shoulder injection verses combined supra scapular and axillary nerve block for adhesive capsulitis: A double-blind Randomized Control Trial

**Public title**  
The Efficacy of intra-articular shoulder injection verses combined supra scapular and axillary nerve block for adhesive capsulitis: A double-blind Randomized Control Trial

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Stage 2-3 AC unilateral No shoulder injuries in the previous three months• Absence of shoulder injections  
Absence of bleeding disorders no prior history of cancer• absence of inflammatory illness history Ages Eligible for Study: 30 Years to 70 Years (Adult, Older Adult) Sexes Eligible for Study: All  
**Exclusion criteria:**  
Malignancy Inflammatory disease

**Age**  
From **30 years** old to **70 years** old

**Gender**  
Both

**Phase**  
1

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **80**  
More than 1 sample in each individual  
Number of samples in each individual: **40**  
N/A

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

**Randomization description**  
computer-generated random numbers will be used

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The participants in the study will not know which treatment they are receiving—whether it is the intra-articular shoulder injection or the combined suprascapular and axillary nerve block. To ensure blinding, both interventions will be performed in a manner that appears identical to the participant. For instance, both procedures will involve a similar preparation process, positioning, and the application of local anesthetic. This approach prevents participants' expectations or psychological effects from influencing the outcomes. The outcome assessor, who is responsible for evaluating the effectiveness of the treatments, will also be blinded to which intervention each participant

received. This means that the assessor will not have access to information regarding the group allocation during the assessment process. Blinding the outcome assessor helps eliminate potential bias in measuring outcomes such as pain, range of motion, and functional recovery, ensuring that the results are based purely on the effects of the interventions rather than on any preconceived notions.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**  
N/A

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

GHURKI TRUST AND TEACHING HOSPITAL

##### Street address

Band Road GT RD-Burki Rd Link, Jallo More Lahore, Punjab

##### City

Lahore

##### Postal code

Jallo More, Lahore 5

#### Approval date

2024-08-26, 1403/06/05

#### Ethics committee reference number

Ref.No.2024/08/R-21

## Health conditions studied

### 1

#### Description of health condition studied

Adhesive capsulitis AC or Frozen Shoulder

#### ICD-10 code

M75.00

#### ICD-10 code description

Adhesive capsulitis of unspecified shoulder

## Primary outcomes

### 1

#### Description

Shouder Pain And Disability, Range of Motion, Quailty of Life

#### Timepoint

2, 4, 6, 8, 10, and 12 weeks

#### Method of measurement

for Shoulder Pain and Disability Index SPADI, for pain assessment VAS, for Range of Motion will be assess by Goniometer. assessing quality of life SF-36 will be used

## Secondary outcomes

### 1

#### Description

The secondary outcome of the study is assessment of quality of life at different intervals. Quality of life will be assessed by SF-36 questionnaire.

#### Timepoint

2nd, 4th, 6th, 8th, and 12th weeks

#### Method of measurement

Quality of life SF-36 The SF-36 will be used to assess quality of life at baseline as well as three weeks, three months, and twelve months after the intervention. 36 items total, divided into eight domains by this widely used self-administered questionnaire: five for vitality, five for mental health, two for bodily pain, two for social function, ten for physical function, four for physical role, three for emotional role, and five for general health. A lower figure indicates a worse situation. From 0 to 100 is the range of scores.

## Intervention groups

### 1

#### Description

Intervention group: We will gather baseline measurements of shoulder discomfort, range of motion (ROM), and functional status in addition to demographic information and medical history. Next, using computer-generated random numbers in a 1:1 ratio, participants will be randomly assigned to two of three treatment groups: intra-articular shoulder injection or combination suprascapular and axillary nerve block. Participants in the combined suprascapular and axillary nerve block group will receive ultrasound-guided nerve blocks that target the corresponding nerves, while those in the intra-articular shoulder injection group will receive a Prednisolone 40mg of 1 ml corticosteroid injection directly into the glenohumeral joint. Suprascapular and axillary nerve blocks are the two forms of nerve blocks used in Group I of this experimental treatment to alleviate shoulder pain. One milliliter of 40 mg Prednisolone and two milliliters of 0.125% bupivacaine and two milliliters of lidocaine 0.125% will be mixed with five milliliters of normal saline. A total of ten milliliters solution six milliliters of solution used for the suprascapular nerve block, and four milliliters of the same substance and for the axillary nerve block. Using the combined effects of a local anesthetic and a corticosteroid to give both instant and long-lasting pain relief, both operations are guided by ultrasonography to assure accurate medication distribution.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: Additionally, an intra-articular shoulder injection is used in Group II of this

investigational treatment to address shoulder pain. Using a combination of a local anesthetic and a corticosteroid to reduce inflammation and give both immediate and long-lasting pain relief, the operation is guided by ultrasonography to ensure exact medicine distribution straight into the shoulder joint. An intra-articular shoulder injection is another name for this course of treatment.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghurki Trust and Teaching Hospital

##### Full name of responsible person

Dr Waqas Ashraf

##### Street address

Jallo More, Lahore 53400, Punjab, Pakistan

##### City

Lahore

##### Postal code

Jallo More, Lahore 5

##### Phone

+92 307 8625941

##### Fax

+92 307 8625941

##### Email

tayyabm851@gmail.com

##### Web page address

<https://www.ghurkitrust.org.pk/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ghurki Trust Teaching Hospital

##### Full name of responsible person

Dr Waqas Ashraf

##### Street address

G.T RD-Burki Rd Link, Band Road, Jallo Morr, Lahore, Pakistan

##### City

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##### Web page address

<https://www.ghurkitrust.org.pk/>

#### Grant name

#### Grant code / Reference number

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

Yes

**Title of funding source**

Ghurki Trust Teaching Hospital

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**City**

Lahore

**Province**

Punjab

**Postal code**

G.T RD-Burki Rd Link

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+92 307 8625941

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**Person responsible for general inquiries****Contact****Name of organization / entity**

Ghurki Trust Teaching Hospital

**Full name of responsible person**

Dr Waqas

**Position**

Consultant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

G.T RD-Burki Rd Link, Band Road, Jallo Morr, Lahore,  
Pakistan

**City**

Lahore

**Province**

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**Person responsible for updating data****Contact****Name of organization / entity**

Ghurki Trust Teaching Hospital

**Full name of responsible person**

Muhammad Tayyeb

**Position**

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**Latest degree**

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**Other areas of specialty/work**

Anesthesiology

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**Web page address**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ghurki Trust Teaching Hospital

**Full name of responsible person**

Dr Waqas

**Position**

Consultant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

G.T RD-Burki Rd Link, Band Road, Jallo Morr, Lahore,  
Pakistan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

The Efficacy of intra articular shoulder injection Verses combined suprascapular and axillary nerve block for adhesive capsulitis: A double blind Randomized Control Trial

**When the data will become available and for how long**

20th January 2025 and so on

**To whom data/document is available**

to the journal while publishing the data

**Under which criteria data/document could be used**

Journal can access to the data after publishing

**From where data/document is obtainable**

To obtain the necessary documents or data files, the applicant should contact the organization directly. The preferred method of communication is via email, which allows for a quick and efficient response. Applicants can also reach out by telephone for urgent inquiries, or by postal mail if a formal request is required. For online requests, visiting the organization's website and following specific procedures is recommended.

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

To obtain data files from Ghurki Hospital, the applicant should follow a few steps. Prepare a formal request detailing the data needed. The preferred method of communication is via email, as it typically offers a quicker response time, ranging from a few hours to a few days. If submitting the request via postal mail, account for additional time due to delivery and internal processing, which can extend the timeline by several weeks. Ghurki Hospital may also offer an online portal for document requests, which is usually the fastest option, providing immediate confirmation and estimated processing times. After submission, the hospital may require further information, such as proof of identity, additional forms, or a processing fee, which could add a few more days to the process. Once approved, the documents or data files will typically be sent via email or through a secure download link. If physical copies are needed, these will be sent by postal mail, with additional time required for delivery. Overall, expect the process to take from one to several weeks, so it's advisable to start the request well in advance of any deadlines.

**Comments**

we are planning to publish it in reputed journal for better clinical practice and EBP