Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 Exlusion 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

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Pakistan

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+92 307 8625941

Email address
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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 assesment of quaility of life at different interval. Quaility of life will assess 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

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Jallo More, Lahore 53400, Punjab, Pakistan

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Web page address
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ghurki Trust Teaching Hospital

Full name of responsible person
Dr Waqas Ashraf

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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
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

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
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Person responsible for scientific inquiries

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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
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