

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

### Comparative effectiveness of spencer technique versus isotonic stretching on pain, Range of Motion, and Shoulder Disability in patients with stage-II Adhesive Capsulitis.

#### Protocol summary

##### Study aim

the aim of the study is to compare the effectiveness of spencer technique and isotonic stretching in patients with stage-II adhesive capsulitis

##### Design

Pragmatic, parallel-group, single-blind, randomized clinical trial

##### Settings and conduct

The trial is conducted in Allied Hospital Faisalabad. Subjects are chosen according to inclusion criteria. Subjects are blinded as they don't know their treatment protocol and group.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria • Patients aged between 40-60 years • Gender included both male and female. • Patients having frozen shoulder of stage 2. • Patient having restricted ROM. Exclusion Criteria • Patient with recent history of surgery. • Patient with Rheumatoid arthritis • Patient with history of any trauma/fracture of shoulder region. • Subject with neurological deficit

##### Intervention groups

Both groups will receive baseline treatment protocol capsular stretching of shoulder joint and isometric strengthening exercise of flexor, extensor, abductors, adductors, external rotators, internal rotators. Group A will be given Spenser Technique for 1 set of 10 repetitions. Group B will be given isotonic stretching for 1 set with 5 repetitions.

##### Main outcome variables

Pain, Range of Motion, Shoulder Disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230518058222N1**

Registration date: **2023-06-12, 1402/03/22**

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

Last update: **2023-06-12, 1402/03/22**

Update count: **0**

##### Registration date

2023-06-12, 1402/03/22

##### Registrant information

###### Name

Rida E Fatima

###### Name of organization / entity

Riphah International University Faisalabad

###### Country

Pakistan

###### Phone

+92 321 6002890

###### Email address

ridaefatima234@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-29, 1402/03/08

##### Expected recruitment end date

2023-09-09, 1402/06/18

##### Actual recruitment start date

2023-05-29, 1402/03/08

##### Actual recruitment end date

2023-09-09, 1402/06/18

##### Trial completion date

2023-09-09, 1402/06/18

##### Scientific title

Comparative effectiveness of spencer technique versus isotonic stretching on pain, Range of Motion, and Shoulder Disability in patients with stage-II Adhesive

|                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Capsulitis.                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Public title</b>                           | spencer technique and isotonic stretching in stage-II Adhesive Capsulitis.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Purpose</b>                                | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Inclusion/Exclusion criteria</b>           | <b>Inclusion criteria:</b> <ul style="list-style-type: none"> <li>• Patients aged between 40-60 years.</li> <li>• Gender included both male and female.</li> <li>• Patients having frozen shoulder of stage-II.</li> <li>• Patient having restricted ROM.</li> </ul> <b>Exclusion criteria:</b> <ul style="list-style-type: none"> <li>• Patient with recent history of surgery.</li> <li>• Patient with Rheumatoid arthritis.</li> <li>• Patient with history of any trauma/fracture of shoulder region.</li> <li>• Patient with neurological deficit.</li> </ul> |
| <b>Age</b>                                    | From <b>40 years</b> old to <b>60 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Gender</b>                                 | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Phase</b>                                  | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Groups that have been masked</b>           | <ul style="list-style-type: none"> <li>• Participant</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Sample size</b>                            | Target sample size: <b>62</b><br>Actual sample size reached: <b>52</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Randomization (investigator's opinion)</b> | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Randomization description</b>              | We did randomization by computer generator method Random allocation software. Unit of randomization is individual. Type of randomization is simple randomization. Software name is random allocation software.                                                                                                                                                                                                                                                                                                                                                     |
| <b>Blinding (investigator's opinion)</b>      | Single blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Blinding description</b>                   | In our study participants are blinded that's why it is single blinded study .participants are unaware of interventions group. They didn't know which group of intervention they received. Investigator, healthcare provider, Data collector, outcome assessor they all are not blinded,                                                                                                                                                                                                                                                                            |
| <b>Placebo</b>                                | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Assignment</b>                             | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Other design features</b>                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Secondary Ids</b>                          | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Ethics committees</b>                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b><u>1</u></b>                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Ethics committee</b>                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Name of ethics committee</b>               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

|                                                                |                                                                        |
|----------------------------------------------------------------|------------------------------------------------------------------------|
| Ethics committee of Riphah International University faisalabad |                                                                        |
| <b>Street address</b>                                          | Riphah international University near fish farm satyana road Faisalabad |
| <b>City</b>                                                    | Faisalabad                                                             |
| <b>Postal code</b>                                             | 38000                                                                  |
| <b>Approval date</b>                                           | 2023-05-29, 1402/03/08                                                 |
| <b>Ethics committee reference number</b>                       | RCRAHS/REC/23/39                                                       |

## Health conditions studied

### 1

#### Description of health condition studied

Stage -II Adhesive Capsulitis

#### ICD-10 code

M75.0

#### ICD-10 code description

Adhesive Capsulitis of unspecified shoulder

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Before intervention and 4 weeks after intervention

#### Method of measurement

Pain will be measured by using Numeric Pain Rating Scale

## Secondary outcomes

### 1

#### Description

Range of Motion at shoulder joint

#### Timepoint

Before intervention and 4 weeks after intervention

#### Method of measurement

Range of motion at shoulder joint will be measured by using goniometer

### 2

#### Description

Shoulder Disability

#### Timepoint

Before intervention and 4 weeks after intervention

#### Method of measurement

Shoulder disability will be measured by using Shoulder Pain and Disability Index

## Intervention groups

### 1

#### Description

Intervention group: Intervention group A is the Spencer technique which target shoulder muscles to improve pain, range of motion and shoulder disability. the dosage was one sets of each 10-15 repetitions within pain-free range.

#### Category

Treatment - Other

### 2

#### Description

Intervention group: Intervention group B is the isotonic stretching which relax the tight muscles to improve pain, range of motion and shoulder disability. The dosage was one sets of each 5 repetitions

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Allied Hospital Faisalabad

##### Full name of responsible person

Dr. Sobia Nawaz

##### Street address

Dr. Tusi Rd, Faisalabad, Punjab

##### City

Faisalabd

##### Postal code

38000

##### Phone

+92 41 9210082

##### Email

info@pmc.edu.pk

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Riphah International University Faisalabad

##### Full name of responsible person

Dr. Sahreen Anwar

##### Street address

Adjacent Fish Farm, Satayana Road, Faisalabad.

##### City

Faisalabad

##### Postal code

38000

##### Phone

+92 41 8777210

##### Email

contact@riphahfsd.edu.pk

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Riphah International University Faisalabad

#### Proportion provided by this source

10

#### 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

Riphah International University Faisalabad

##### Full name of responsible person

Rida E Fatima

##### Position

Lacturer

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

house no. 692-B People's Colony#1 Faisalabad

##### City

Faisalabad

##### Province

Punjab

##### Postal code

38000

##### Phone

+92 321 6002890

##### Email

Ridaefatima234@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Riphah International University Faisalabad

##### Full name of responsible person

Rida E Fatima

##### Position

Lecturer

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

House no. 692-B People's Colony#1, Faisalabad

##### City

Faisalabad  
**Province**  
Punjab  
**Postal code**  
38000  
**Phone**  
+92 321 6002890  
**Email**  
Ridaefatima234@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Riphah International University Faisalabad  
**Full name of responsible person**  
Rida E Fatima  
**Position**  
Lecturer  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiotherapy  
**Street address**  
House no. 692-B people's colony#1, Faisalabad  
**City**  
Faisalabad  
**Province**  
Punjab  
**Postal code**  
38000  
**Phone**  
+92 321 6002890  
**Fax**  
**Email**  
Ridaefatima234@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Sharing IPD may raise privacy and confidentiality concerns, especially when the data contains sensitive or personally identifiable information. There may be legal or ethical obligations to protect the privacy of the participants, and sharing their data could violate those obligations.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

The data set of IPD will be shared for primary outcomes only

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

starting in September 2023

### To whom data/document is available

Data set will be available for academic persons

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

The documents will be used for further research purposes

### From where data/document is obtainable

The data will be provided from email Id  
ridaefatima234@gmail.com

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

The applicant should send an email for requesting the documents and request will be followed within 72 hours.

### Comments