# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## A single-blind randomized clinical trial comparing calf muscle stretches with cryotherapy, eccentric exercises with cryotherapy, and combined therapy on pain, functional disability, and ankle range of motion in young athletes with Sever’s disease

## Protocol summary


**Study aim**

To evaluate and compare the effectiveness of calf muscle stretches with cryotherapy, eccentric exercises with cryotherapy, and their combination (combined therapy with cryotherapy) on pain intensity, functional disability, and ankle range of motion in young athletes.

**Design**

Single-blind, parallel-group randomized clinical trial

**Settings and conduct**

This single-blind, parallel-group randomized clinical trial was conducted at a school sports complex in Gujranwala, Pakistan (June–September 2025). Participants attended three supervised 17–20minute sessions per week for six weeks (18 total sessions). Outcomes were assessed at baseline and within 48 hours post-intervention.

**Participants/Inclusion and exclusion criteria**

Of 150 young athletes screened, inclusion criteria were: age 8–15 years, heel pain ≥2 weeks, pain at Achilles insertion on the calcaneus, and heel tenderness/swelling. Exclusion criteria were recent heel trauma/fracture, direct injury, neurological disorders, or systemic disorders.

**Intervention groups**

All groups received 18 sessions over six weeks (three sessions/week, 17–20 minutes each, including 2–3 minute warm-up). Cryotherapy (cold pack to heel for 5–10 minutes) was applied after each session. - Group A (Stretches): Three calf stretches (standing wall, bent-knee, soleus) — 3 sets of 6–10 repetitions, hold 20–30 seconds. Group B (Eccentric): Heel drops (3×10), sumo squats with pulses (3×6), and eccentric toe walk (3×10–15 steps). Group C (Combined): Both stretch and eccentric protocols.

**Main outcome variables**

Primary outcomes: pain intensity (NPRS, 0–10) and functional disability (OXAFQ, 0–100). Secondary outcome: ankle ROM (dorsiflexion, plantar flexion, inversion, eversion) measured via goniometer. Assessments at baseline and 48 hours post-intervention (6 weeks).


## General information

**Reason for update**

**Acronym**

None

**IRCT registration information**

IRCT registration number: **IRCT20260529069564N1**
Registration date: **2026-06-02, 1405/03/12**
Registration timing: **retrospective**

Last update: **2026-06-02, 1405/03/12**
Update count: **0**

**Registration date**

2026-06-02, 1405/03/12

**Registrant information**


**Name**

Sajjan Iqbal Memon

**Name of organization / entity**

Chiniot General Hospital, Korangi

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Pakistan

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2025-06-01, 1404/03/11

**Expected recruitment end date**

2025-09-01, 1404/06/10

**Actual recruitment start date**

2025-06-01, 1404/03/11

**Actual recruitment end date**

2025-06-01, 1404/03/11

**Trial completion date**

2025-09-01, 1404/06/10

**Scientific title**

A single-blind randomized clinical trial comparing calf muscle stretches with cryotherapy, eccentric exercises with cryotherapy, and combined therapy on pain, functional disability, and ankle range of motion in young athletes with Sever’s disease

**Public title**

Effects of Calf Muscle Stretches and Eccentric Exercises Along With Cryotherapy on Sever's Disease in Local Young Players of Gujranwala: A Randomized Clinical Trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Children and adolescents aged 8–15 years Clinically diagnosed with Sever’s disease (calcaneal apophysitis) History of heel pain for at least two weeks Pain localized over the posterior calcaneus at the Achilles tendon insertion Heel tenderness and swelling on palpation Physically active young athletes participating in sports activities Willingness of parents/legal guardians to provide written informed consent and child assent

**Exclusion criteria:**

Recent trauma or fracture involving the heel Direct injury explaining heel pain Neurological disorders Systemic inflammatory or musculoskeletal disorders Previous lower-limb surgery Current participation in another rehabilitation or clinical trial program

**Age**

From **8 years** old to **15 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **150**

Actual sample size reached: **140**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Method of randomization: Not explicitly named (simple or block not specified), but participants were randomly assigned in a 1:1:1 ratio using an online tool Unit of randomization: Individual participant Randomization strata: None described Tools used for randomization: Online Research Randomizer tool (www.randomizer.org) How the random sequence was built: The tool generated the allocation sequence; unique identification codes were assigned to all participants Allocation concealment: Yes — outcome assessors were blinded to group allocation. However, participants and therapists could not be blinded due to the nature of exercise interventions

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study employed a single-blind design. Due to the nature of the interventions, participants and treating physiotherapists cannot be blinded to group allocation. However, the assessor responsible for collecting outcome measures (pain intensity, functional disability, and ankle range of motion) will be blinded to treatment allocation throughout the study. Participants will be instructed not to disclose their assigned intervention to the assessor. In addition, data analysis will be conducted using coded group labels (e.g., Group A, B, and C) to maintain assessor and analyst blinding until the completion of statistical analyses.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

This is a three-arm, single-blind, parallel-group randomized controlled trial. Eligible participants with clinically diagnosed Sever's disease will be randomly allocated in a 1:1:1 ratio to one of three intervention groups: (1) calf muscle stretches with cryotherapy, (2) eccentric exercises with cryotherapy, or (3) combined calf muscle stretches and eccentric exercises with cryotherapy. Interventions will be administered three times weekly for six weeks. Outcome assessments will be conducted at baseline and after completion of the intervention period by an assessor blinded to group allocation. Primary outcomes include pain intensity and functional disability, while ankle range of motion will be assessed as a secondary outcome.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Institutional Review Board of Gujranwala Institute of Medical and Emerging Sciences (GIMES main camp

**Street address**

GIMES main campus, Ali Pur Chatha Road, near Gujranwala Medical College, Gujranwala

**City**

Gujranwala

**Postal code**

52080

**Approval date**

2025-04-10, 1404/01/21

**Ethics committee reference number**

GIMES/REC/S/25-00905

## Health conditions studied

### 1

**Description of health condition studied**
Sever's disease (calcaneal apophysitis) in physically active children and adolescents
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Pain Intensity
**Timepoint**
at Baseline (pre-intervention) and within 48 hours after the final session (post-intervention, i.e., at 6 weeks).
**Method of measurement**
Numeric Pain Rating Scale

### 2

**Description**
Functional Disability
**Timepoint**
at Baseline (pre-intervention) and at post-intervention (6 weeks).
**Method of measurement**
Oxford Ankle Foot Questionnaire for Children (OXAFQ) – a 14-item validated questionnaire.

## Secondary outcomes

### 1

**Description**
Ankle Range of Motion
**Timepoint**
at Baseline (pre-intervention) and at post-intervention (6 weeks)
**Method of measurement**
using Active ankle dorsiflexion, plantar flexion, inversion, and eversion measured in degrees utilizing a universal goniometer

## Intervention groups

### 1

**Description**
Intervention group:
**Category**
Rehabilitation

### 2

**Description**
Intervention group:
**Category**
Rehabilitation

### 3

**Description**
Intervention group:
**Category**
Rehabilitation

### 4

**Description**
Control group:
**Category**
Treatment - Other

### 5

**Description**
Control group:
**Category**
Treatment - Other

### 6

**Description**
Control group:
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Quaid-e-Azam Divisional School
**Full name of responsible person**
Dr. Shumana Zakaullah
**Street address**
Quaid-e-Azam Divisional School, near Railway Station, Gujranwala, Punjab, Pakistan
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Gujranwala Institute of Medical and Emerging

Sciences, Gujranwala, Pakistan

**Full name of responsible person**
The principal

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**Web page address**
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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
No

**Title of funding source**
Dissertation

**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**
Chiniot General Hospital, Korangi

**Full name of responsible person**
Dr Sajjan Iqbal Memon

**Position**
Senior Officer, Quality & Patient Safety

**Latest degree**
Master

**Other areas of specialty/work**
Health and Hospital Administration

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https://scholar.google.com/citations?user=9FGhVmUAAAAJ&hl=en

## Person responsible for scientific inquiries

**Contact**

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Gujranwala Institute of Medical and Emerging Sciences

**Full name of responsible person**
Shumana Zakaullah

**Position**
Head of Department

**Latest degree**
Master

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Physiotherapy

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## Person responsible for updating data

**Contact**

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Gujranwala Institute of Medical and Emerging Sciences

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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**

Deidentified individual participant data (IPD) collected for all primary and secondary outcomes, including: NPRS pain scores, OXAFQ functional disability scores, and ankle range of motion measurements (dorsiflexion, plantar flexion, inversion, eversion) at baseline and 6 weeks post-intervention. Also includes demographic data (age, gender) and group allocation.

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

Data will become available starting 6 months after publication of the main trial results and will remain available for 5 years.

**To whom data/document is available**

Data will be shared with researchers working in academic institutions who provide a methodologically sound proposal. Requests from commercial entities will be considered on a case-by-case basis.

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

Data may be used for systematic reviews, meta-analyses, secondary analyses of pediatric musculoskeletal conditions, and validation of outcome measures. Requests will be reviewed by the principal investigators (Dr. Shumana Zakaullah, Dr Saada Asif and Dr Sajjan Iqbal) based on scientific merit and ethical approval from the requester's institutional review board.

**From where data/document is obtainable**

Requests should be directed to the corresponding author: Contact Person: Dr. Shumana Zakaullah Email: shumanazakaullah@gmail.com Address: Department of Physical Therapy, Gujranwala Institute of Medical and Emerging Sciences (GIMES), Ali Pur Chatha Road, near Gujranwala Medical College, Gujranwala, Punjab, 52250, Pakistan

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

Applicants must submit a written request via email to the corresponding author, including a detailed research proposal, ethical approval letter, and signed data sharing agreement. Requests will be reviewed within 4–6 weeks. Approved applicants will receive deidentified data via secure encrypted file transfer.

**Comments**

None