Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
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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?
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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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

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