Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effect of Six Weeks of Corrective Exercises Combined with Hydrolyzed Collagen and Vitamin C Supplementation on Pain, Function, and Quality of Life in Female Athletes Players with Achilles Tendinopathy

Protocol summary

Study aim

The Effect of Six Weeks of Corrective Exercises Combined with Hydrolyzed Collagen and Vitamin C Supplementation on Pain, Function, and Quality of Life in Female Athletes Players with Achilles Tendinopathy

Design

The study design is a phase 3, placebo-controlled, single-blind (participant-blinded only), randomized clinical trial in which 30 participants will be allocated into two equal groups—experimental (n=15) and control (n=15)—using block randomization.

Settings and conduct

The study will be conducted at the Faculty of Sport Sciences, Razi University (Kermanshah); exercise sessions take place in the corrective exercise hall, while assessments and supplement distribution are performed in the motion analysis laboratory and clinic by a blinded assessor.

Participants/Inclusion and exclusion criteria

Inclusion Conditions 1. Active ankle range of motion with at least ۱۰ degrees of dorsiflexion to ensure proper execution of corrective exercises. 2. Written commitment to attend all training sessions regularly (at least ۸۰% attendance) and to refrain from any concurrent therapeutic interventions for the Achilles. Exclusion Conditions Occurrence of any acute injury in the lower extremity (knee, hip, or back) within ۴ weeks prior to the study that affects gait pattern. History of taking supplements containing collagen, vitamin C, or other tendon-affecting compounds within ۴ weeks before study initiation.

Intervention groups

In this trial, the experimental group will receive 30 grams of hydrolyzed collagen plus 500 mg of vitamin C daily, while the control group will receive a maltodextrin placebo plus vitamin C, with both groups consuming their respective supplements one hour prior to performing three weekly sessions of corrective exercises (eccentric, balance, and neuromuscular) based on the Alfredson protocol.

Main outcome variables

Pain, Function, QoL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260605069646N1**
Registration date: **2026-07-10, 1405/04/19**
Registration timing: **prospective**

Last update: **2026-07-10, 1405/04/19**
Update count: **0**

Registration date

2026-07-10, 1405/04/19

Registrant information

Name
Asal Besanj
Name of organization / entity
Razi university
Country
Iran (Islamic Republic of)
Phone
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Email address
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-01, 1405/05/10

Expected recruitment end date

2026-10-02, 1405/07/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Six Weeks of Corrective Exercises Combined with Hydrolyzed Collagen and Vitamin C Supplementation on Pain, Function, and Quality of Life in Female Athletes Players with Achilles Tendinopathy

Public title
Effect of Six-Week Corrective Exercise and Collagen-Vitamin C Supplementation on Pain, Function, and Quality of Life in Female Athletes with Achilles Tendinopathy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Clinical diagnosis of mid-portion Achilles tendinopathy (pain and tenderness ۲–۶ cm above insertion) confirmed by a specialist or imaging (ultrasound/MRI). Recreational to semi-professional female athletes with at least ۳ exercise sessions per week, aged ۱۸–۴۵ years. Pain intensity ≥ ۳/۱۰ on Visual Analogue Scale (VAS) during daily or sports activity for at least the past ۴ weeks.

Exclusion criteria:
History of Achilles surgery, complete rupture, corticosteroid or PRP injection in the last ۶ months Systemic diseases affecting tissue repair (uncontrolled diabetes, rheumatoid arthritis, renal failure) or allergy to collagen/vitamin C. Pregnancy, lactation, regular use of analgesics/NSAIDs in the ۲ weeks prior to the study, or concurrent participation in other targeted physiotherapy/exercise interventions for Achilles.

Age
From **18 years** old to **28 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed using block randomization with block sizes of 4 (or 6). The allocation sequence is generated by statistical software or a random number table and placed in sequentially numbered, opaque, sealed envelopes. Group allocation is carried out by an independent individual (not involved in assessment or intervention delivery) to ensure allocation concealment. The outcome assessor and participants remain blinded to group assignment (assessor-blinded design).

Blinding (investigator's opinion)
Single blinded

Blinding description
Blinding is applied only to participants. Both groups receive the same corrective exercise program, but participants are unaware of which supplement they are taking. The active supplement (collagen + vitamin C) and placebo are completely identical in appearance, odor, taste, color, size, and packaging, and are coded by an individual independent of the research team. Thus, participants do not know whether they are in the supplement or placebo group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Razi University of Kermanshah

Street address
No. 8, Razi University, Daneshgah Boulevard, Taq Bostan Street, Kermanshah, Iran

City
Kermanshah

Province
Kermanshah

Postal code
6714414971

Approval date
2026-05-12, 1405/02/22

Ethics committee reference number
IR.RAZI.REC.1405.011

Health conditions studied

1

Description of health condition studied
Female Athletes

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain

Timepoint
Measurement time points are two: baseline (week 0) and post-test (week 6).

Method of measurement

pain via Visual Analogue Scale (VAS, 0-10) during sports activity

2

Description
Achilles-specific function
Timepoint
Measurement time points are two: baseline (week 0) and post-test (week 6).
Method of measurement
function via the VISA-A questionnaire (8 items, 0-100)

3

Description
Quality of life/daily functional
Timepoint
Measurement time points are two: baseline (week 0) and post-test (week 6).
Method of measurement
Quality of life/daily function via the Lower Extremity Functional Scale (LEFS, 20 items, 0-80)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group (n=15) consumes 30 g of hydrolyzed collagen plus 500 mg of vitamin C one hour before each corrective exercise session, performed three times per week for six weeks.
Category
Prevention

2

Description
Control group: The control group (n=15) consumes a placebo (maltodextrin plus 500 mg of vitamin C) one hour before each corrective exercise session, performed three times per week for six weeks, following the same exercise protocol as the intervention group.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Ubiversity
Full name of responsible person
Asal Basenj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Kivan Amini
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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
Razi Univeristy
Proportion provided by this source
100
Public or private sector
Public
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
Razi University
Full name of responsible person
Hidar Menochari
Position
Assistant Professor
Latest degree

Ph.D.

Other areas of specialty/work
Pathology and Corrective Exercises

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Position
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Latest degree
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Other areas of specialty/work
Pathology and Corrective Exercises

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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
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data will be recorded in the SPSS software and will be available

When the data will become available and for how long
Availability will start nine months after publishing all papers

To whom data/document is available
Only available for researchers in academic and scientific institutions

Under which criteria data/document could be used
All data can be used as a reference

From where data/document is obtainable
asalbesanj@gmail.com

What processes are involved for a request to access data/document
All data can be used as a reference

Comments