Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of a drink containing basil extract in reducing the severity of delayed onset muscle soreness: A randomized controlled trial

Protocol summary

Study aim
Investigating the effect of daily consumption of a fortified drink based on basil extract in reducing the severity of delayed onset muscle soreness

Design
Interventional trial, randomized, triple-blind, parallel allocation with a 1:1 ratio, expected sample size of 80 people.

Settings and conduct
بیمارستان رازی، ایلام، ایران، تحت نظارت دانشگاه علوم پزشکی ایلام

Participants/Inclusion and exclusion criteria
Adults 18 years and older with regular physical activity (at least 3 sessions per week in the past 6 months), normal body mass index, and normal liver, kidney, and thyroid function. No regular use of NSAIDs or corticosteroids, no participation in other clinical trials in the past 3 months, no use of hormonal supplements, and no sensitivity to ingredients in the drink. Exclusion of individuals with sports injuries, diabetes, autoimmune diseases, or altered liver, kidney, and thyroid function.

Intervention groups
Intervention group: One 250 ml drink daily containing basil extract, whey protein, creatine, L-glutamine, ginger extract and vitamin C for 4 weeks, consumed 30 minutes after training or on non-training days between 10 am and 12 am. Control group: Placebo drink identical in appearance, taste, color and volume, without active ingredients, with the same consumption schedule.

Main outcome variables
Muscle pain intensity was measured with a visual analog scale (VAS) before the start of the study and 4 weeks after the start of the intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211110053030N11**
Registration date: **2025-11-15, 1404/08/24**
Registration timing: **prospective**

Last update: **2025-11-15, 1404/08/24**
Update count: **0**

Registration date
2025-11-15, 1404/08/24

Registrant information

Name
Alireza Vasiee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 84 3222 7091

Email address
rezawest10@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-11-22, 1404/09/01

Expected recruitment end date
2026-01-28, 1404/11/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of a drink containing basil extract in reducing the severity of delayed onset muscle soreness: A randomized controlled trial

Public title
The effectiveness of a drink containing basil extract in

reducing the severity of delayed onset muscle soreness: A randomized controlled trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Regular physical activity, at least 3 exercise sessions per week, started within the last 6 months Normal body mass index Normal liver, kidney, thyroid function No regular use of NSAIDs or corticosteroids in the 7 days prior to the start of the study Not participating in any other clinical study in the past 3 months Not taking hormonal supplements Following the training cycle according to the protocol Absence of stomach and intestinal ulcers within the last 3 months

Exclusion criteria:

Sports injury during intervention Diagnosed with diabetes Diagnosed with autoimmune diseases Known history of allergy to basil, whey protein, creatine, glutamine, ginger, or vitamin C Administration of NSAIDs or corticosteroids during the intervention Changes in liver, kidney, and thyroid function in interventional medicine

Age

From **18 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to the intervention and control groups using a block randomization method with a block size of 4. The randomization list will be prepared using Random Allocation Software (version 1.0) by an independent individual outside the implementation process. Random codes will be placed in opaque, sealed, numbered envelopes and returned in the order in which the participant entered. The study administrator, participant, and statistical analyst will not have access to the group allocation.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is conducted in a triple-blind manner. Participants, the conducting researcher (responsible for implementing the intervention and collecting data), and the data analyst are unaware of their group allocation (intervention or control). The intervention drink and the control drink (placebo) are completely identical in terms of color, taste, odor, volume, packaging type, and presentation, and there are no recognizable features to distinguish between the two drinks. Allocation codes are generated by an independent person who is not involved in the implementation and analysis of the study and are kept in opaque, sealed, and numbered envelopes. Opening the codes will only be permitted after the data analysis is complete.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ilam University of Medical Sciences

Street address

Bangangab, Ilam University of Medical Sciences, Research and Technology Building

City

Ilam

Province

Ilam

Postal code

6939177143

Approval date

2025-10-21, 1404/07/29

Ethics committee reference number

IR.MEDILAM.REC.1404.175

Health conditions studied

1

Description of health condition studied

Muscle pain

ICD-10 code

M79.1

ICD-10 code description

Myalgia

Primary outcomes

1

Description

Pain

Timepoint

Before the intervention and 4 weeks after the start of the intervention

Method of measurement

Visual analogue scale (VAS) pain assessment questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in this group will receive one serving of a basil extract-based fortified drink (with a final volume of 250 ml) daily, the formulation of which will include: standardized basil extract (equivalent to 500 mg of flavonoids), 20-25 g of whey protein isolate, 3 g of creatine monohydrate, 5 g of microencapsulated L-glutamine, standardized ginger extract (at least 3 mg of gingerol), 200 mg of vitamin C, natural sweetener, and 10-15 ml of lemon juice to adjust pH. This combination will be consumed for four weeks, 30 minutes after training or on non-training days between 10 am and 12 am.

Category

Rehabilitation

2

Description

Control group: Participants in this group will receive a placebo that will be identical in appearance, color, volume (250 ml), and taste to the intervention drink, but will lack any active ingredients (including basil extract, protein, creatine, L-glutamine, ginger extract, and vitamin C). The drink will contain only water, a very small amount of natural flavoring, and an inert sweetener. The placebo will also be consumed for four weeks at the same time as the intervention group (30 minutes after training or on non-training days between 10 a.m. and 12 p.m.).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Alireza Vasiee

Street address
Banganjab, end of Pahoehoeh Boulevard, Razi Hospital

City
Ilam

Province
Ilam

Postal code
6931975397

Phone
+98 84 3224 8553

Email
rezawest10@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ilam University of Medical Sciences

Full name of responsible person
Jamil Sadeghifar

Street address
Pazhohesh Boulevard

City
Ilam

Province
Ilam

Postal code
6939177143

Phone
+98 84 3223 5724

Email
jamil.sadeghifar@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Ilam University of Medical Sciences

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
Ilam University of Medical Sciences

Full name of responsible person
Alireza Vasiee

Position
Nursing Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Danesh square, Hoveizeh st, 17th avenue

City
Ilam

Province
Ilam

Postal code

6931373847

Phone
+98 84 3222 7091

Fax

Email
rezawest10@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ilam University of Medical Sciences

Full name of responsible person
Alireza Vasiee

Position
Nursing Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Danesh square, Hoveizeh st, 17th avenue

City
Ilam

Province
Ilam

Postal code
6931373847

Phone
+98 84 3222 7091

Fax

Email
rezawest10@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ilam University of Medical Sciences

Full name of responsible person
Alireza Vasiee

Position
Nursing Instructor

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Danesh square, Hoveizeh st, 17th avenue

City
Ilam

Province
Ilam

Postal code
6931373847

Phone
+98 84 3222 7091

Fax

Email
rezawest10@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
At the end of the study, a decision will be made by the research team.

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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available