

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Combined effects of creatine and paracetamol on muscular performance, fatigue, and recovery in resistance-trained athletes

Protocol summary

Study aim

To investigate the combined effects of creatine monohydrate and paracetamol supplementation on muscular performance, fatigue reduction, and recovery improvement in male athletes

Design

Controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 30 athletes. Block randomization was performed using Random Allocation Software.

Settings and conduct

This randomized, double-blind clinical trial was conducted at the gymnasium of Islamic Azad University, Ilkhichi Branch. Assessments included muscle performance, fatigue, and recovery at baseline and week 8. Blinding was performed for participants and outcome assessors using placebos with identical appearance, color, and taste.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy male athletes aged 18 to 30 years; at least 3 years of regular specialized training experience in endurance or strength sports; absence of chronic or acute diseases. Exclusion criteria: History of acute musculoskeletal injury in the past 6 months; use of creatine supplements, paracetamol, steroids, or interfering drugs/supplements in the past 3 months.

Intervention groups

Intervention Group: Daily oral creatine monohydrate supplementation (Karen Pharma) for 8 weeks (5-day loading at 20 g/day, 35-day maintenance at 5 g/day) plus 500 mg paracetamol (Amin Pharma) 1 hour pre-exercise, alongside resistance training (8 weeks, 3 sessions/week). Control Group: Identical placebos (Amin Pharma) with the identical training protocol.

Main outcome variables

Maximal muscular strength (1RM), muscular fatigue index, delayed onset muscle soreness (DOMS), and serum creatine kinase (CK) level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240603061995N4**

Registration date: **2026-08-14, 1405/05/23**

Registration timing: **registered_while_recruiting**

Last update: **2026-08-14, 1405/05/23**

Update count: **0**

Registration date

2026-08-14, 1405/05/23

Registrant information

Name

Morteza Jourkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3443 9830

Email address

mjourkesh@ut.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-19, 1404/11/30

Expected recruitment end date

2026-09-21, 1405/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combined effects of creatine and paracetamol on muscular performance, fatigue, and recovery in resistance-trained athletes		match active supplements in appearance, color, taste, smell, and packaging, prepared, coded, and distributed by an independent third party. Emergency unblinding is available via study physician and ethics committee if needed.	
Public title	Investigating the effect of creatine and paracetamol in resistance training	Placebo	Used
Purpose	Supportive	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Gender: Male Age range: 18 to 30 years At least 3 years of regular specialized training experience in endurance or strength sports Complete physical health and absence of chronic or acute diseases Commitment to strictly adhere to the training program, diet, and intervention protocol Exclusion criteria: Presence of chronic or serious diseases (cardiovascular, hepatic, renal, or other conditions affecting athletic performance) History of acute musculoskeletal injury in the past 6 months Regular use of interfering medications or supplements (such as steroids, potent antioxidants, creatine, or paracetamol) in the past 3 months	Other design features	
Age	From 18 years old to 30 years old	Secondary Ids	
Gender	Male	empty	
Phase	3	Ethics committees	
Groups that have been masked	• Participant • Care provider • Investigator • Outcome assessor • Data analyser	1	
Sample size	Target sample size: 30	Ethics committee	
Randomization (investigator's opinion)	Randomized	Name of ethics committee	
Randomization description	Participants were allocated to the study groups (15 in the experimental group and 15 in the control group) using the balanced block randomization method with variable block sizes of 2 and 4. The randomization sequence was generated using Random Allocation Software (version 2.0.0). To ensure allocation concealment, the generated sequences were placed in sequentially numbered, opaque, sealed envelopes (SNOSE) by a third party who was not involved in the study. Envelopes were opened sequentially only after the completion of baseline assessments at the time of each participant's definitive entry into the study, ensuring that the investigator responsible for enrollment and assessment remained blinded to the group assignment until the last moment.	Research Ethics Committees of Islamic Azad University-Tabriz	
Blinding (investigator's opinion)	Double blinded	Street address	
Blinding description	This is a double-blind trial. Participants, principal investigator, care providers, outcome assessors, and data analysts are blinded to group allocation. Placebos	Islamic Azad University, Tabriz Medical Sciences Branch Sahraei Ahar Intersection, Basmenj Road, Tabriz, Iran	
		City	
		Tabriz	
		Province	
		East Azarbaijan	
		Postal code	
		5159115705	
		Approval date	
		2025-05-27, 1404/03/06	
		Ethics committee reference number	
		IR.IAU.TABRIZ.REC.1404.118	
		Health conditions studied	
		1	
		Description of health condition studied	
		Athletic performance and muscle fatigue in healthy athletes	
		ICD-10 code	
		ICD-10 code description	
		Primary outcomes	
		1	
		Description	
		Maximal muscular strength	
		Timepoint	
		Measurement of muscle performance, fatigue, and recovery at the beginning of the study (before the start of intervention) and 8 weeks after the start of intervention.	
		Method of measurement	
		One-repetition maximum test in squat, bench press, and deadlift using standard protocol.	

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Description

Muscular fatigue index

Timepoint

Baseline (before the start of intervention) and after the end of 8 weeks of intervention

Method of measurement

Repetitions in final sets or fatigue ratio during supervised sessions

3

Description

Delayed onset muscle soreness

Timepoint

Measurement of muscle performance, fatigue, and recovery at the baseline (before the start of intervention) and after the end of 8 weeks of intervention

Method of measurement

Visual Analogue Scale or numerical rating scale (0–10)

4

Description

Serum creatine kinase level

Timepoint

Measurement of muscle performance, fatigue, and recovery at the beginning of the study (before the start of intervention) and after the end of 8 weeks of intervention.

Method of measurement

Venous blood sampling and enzymatic or immunoassay analysis in accredited lab.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daily oral consumption of creatine monohydrate (Karen Pharma) for 8 weeks; including a 5-day loading phase (20 g/day in four 5-g doses as water-soluble powder) followed by a maintenance phase (5 g/day in a single dose). Simultaneously, daily oral consumption of 500 mg paracetamol capsules (Amin Pharma) 1 hour before exercise for 8 weeks. The concurrent resistance training protocol consists of 8 weeks, 3 sessions per week, 60 minutes per session (intensity of 70 to 80 percent of 1-repetition maximum).

Category

Other

2

Description

Control group: Daily oral consumption of placebos consisting of starch capsules and powders with identical appearance, color, and concentration to the main

supplement and medication (Amin Pharma) with the exact same dosage, frequency, and timing as the intervention group for 8 weeks. The concurrent resistance training protocol is performed exactly identical to the intervention group (8 weeks, 3 sessions per week, 60 minutes per session, at an intensity of 70 to 80 percent of 1-repetition maximum).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Ilkhichi Branch

Full name of responsible person

Asghar Mohammadian

Street address

Islamic Azad University Ilkhichi Branch Complex, Imam St., Ilkhichi, East Azerbaijan, Ilkhichi

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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?

Yes

Title of funding source

Islamic Azad University

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

2**Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Asghar Mohammadian

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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

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Morteza Jourkesh

Position

Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Faculty Member

Latest degree

Ph.D.

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Postal code

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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

Due to ethical considerations and the need to protect participant confidentiality, as well as the absence of explicit informed consent for sharing individual data, there is no plan to share IPD. Additionally, resources for complete data anonymization are not 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

De-identified Individual Participant Data (IPD) will be made available after study completion and publication of the main article. Includes demographic data, primary outcomes, and laboratory results. Exact repository and timeline have not been finalized yet.

When the data will become available and for how long

6 months after publication of the main article in a peer-reviewed scientific journal.

To whom data/document is available

Academic and scientific researchers upon written request and approval by the study ethics committee.

Under which criteria data/document could be used

For non-commercial scientific research, meta-analyses, and studies related to muscular performance, fatigue, and recovery. Use is permitted only with proper citation of the original study and under a signed data use agreement.

From where data/document is obtainable

To access non-confidential data and the data dictionary, submit a written request to the corresponding author via email (mjourkesh@ut.ac.ir). Data will be available via Figshare after ethics committee approval.

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

Requests for access to the study protocol must be submitted in writing via email to the principal investigator (principal investigator's email address), including the purpose of use. The research team will review the request within 10 working days and provide the protocol if approved.

Comments