Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Recruitment complete

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

Public title
Investigating the effect of creatine and paracetamol in resistance training
Purpose
Supportive
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
Age
From **18 years** old to **30 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind trial. Participants, principal investigator, care providers, outcome assessors, and data analysts are blinded to group allocation. Placebos 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.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Islamic Azad University-Tabriz
Street address
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.

2

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 Ilkhchi Branch Complex, Imam St., Ilkhchi, East Azerbaijan, Ilkhichi
City
Ilkhichi
Province
East Azarbaijan
Postal code
5176678381
Phone
+98 938 278 4093
Email
a.mohammadian@iau.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Asghar Mohammadian
Street address
Islamic Azad University Ilkhchi Branch Complex, Imam St., Ilkhchi, East Azerbaijan ,Ilhichi
City
Tabriz
Province
East Azarbaijan
Postal code
5358114418
Phone
+98 41 4233 4121
Email
ilkhchi@cms.iau.ir
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
Street address
Islamic Azad University, Tabriz-Urmia Highway, Ilkhichi Town
City
Ilkhichi
Province
East Azarbaijan
Postal code
5358114418
Phone
+98 41 3342 1214
Email
ilkhichi@cms.iau.ir
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
Street address
Islamic Azad University Ilkhchi Branch Complex, Imam St., Ilkhchi, East Azerbaijan, Ilkhchi
City
tehran
Province
East Azarbaijan
Postal code
5358114418
Phone
04133421214-7
Email
mjourkesh@ut.ac.ir

Person responsible for scientific 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
Street address
No.34, Shahid Salimi alley, Loghmane Hakim avenue, Jalaliyeh street, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5176678381
Phone
+98 41 3443 9830
Email
mjourkesh@ut.ac.ir

Person responsible for updating data

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
Street address
No.34, Shahid Salimi alley, Loghmane Hakim avenue, Jalaliyeh street, Tabriz
City
Tabriz

Province
East Azarbaijan
Postal code
5176678381
Phone
+98 41 3443 9830
Email
mjourkesh@ut.ac.ir

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