# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 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**