

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Investigating the effects of creatine supplementation on serum testosterone, dihydrotestosterone levels, and hair density in strength athletes: A double-blind clinical trial study

#### Protocol summary

##### Study aim

The aim of this study is to investigate the effects of creatine supplementation on male pattern baldness (androgenetic alopecia) in male athletes.

##### Design

This study is designed as a randomized, double-blind, parallel clinical trial.

##### Settings and conduct

Conducted in-person at the Iran Center for Dermatology and Hair Research.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Gender: Males aged between 18 and 45 years. General Health: Healthy individuals without chronic diseases or metabolic disorders. Hair Loss Status: Participants must not exhibit early signs of male pattern baldness (androgenetic alopecia). Athletic Status: Participants must have been regularly engaged in resistance training (e.g., bodybuilding) for at least one year. No Recent Supplement Use: Participants must not have used any creatine supplements or hair loss-related medications for at least one month prior to the study. Exclusion Criteria: History of Hair-Related Diseases: Individuals with skin diseases or conditions that could affect hair loss, such as alopecia areata. Current Medication or Supplement Use: Individuals currently taking medications affecting hormones or other supplements related to hair loss. specific medical conditions that could interfere with creatine supplementation.

##### Intervention groups

Creatine Supplement Group: Participants in this group will receive a creatine supplement. Placebo Group: Participants in this group will receive a placebo

##### Main outcome variables

Change in hair density; Rate of progression or reduction in male pattern baldness; Changes in serum testosterone and dihydrotestosterone levels; Adverse effects related

to creatine or placebo consumption.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240814062762N1**

Registration date: **2024-08-31, 1403/06/10**

Registration timing: **prospective**

Last update: **2024-08-31, 1403/06/10**

Update count: **0**

##### Registration date

2024-08-31, 1403/06/10

##### Registrant information

##### Name

Mohammadyasin Lak

##### Name of organization / entity

Sport Sciences Research Institute of Iran, Tehran, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6609 1745

##### Email address

yasinlakifbb@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-10-01, 1403/07/10

##### Expected recruitment end date

2024-10-11, 1403/07/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the effects of creatine supplementation on serum testosterone, dihydrotestosterone levels, and hair density in strength athletes: A double-blind clinical trial study

**Public title**  
The effects of creatine supplementation on male pattern baldness in male resistance athletes

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
General Health Status: Healthy individuals without chronic diseases or metabolic disorders. Male Pattern Baldness: Participants must not exhibit early signs of male pattern baldness (androgenetic alopecia). Sporting Activity: Individuals must have been regularly engaged in resistance training (e.g., bodybuilding) for at least one year. No Recent Supplement Use: Individuals must not have used any creatine supplements or hair loss-related medications (such as finasteride or minoxidil) for at least one month prior to the study.  
**Exclusion criteria:**  
History of Hair-Related Diseases: Individuals with skin diseases or other conditions that could affect hair loss, such as alopecia areata. Current Medication or Supplement Use: Current users of medications affecting hormones or other supplements related to hair loss. Advanced Hair Loss: Individuals with advanced hair loss (Norwood stage 5 or above), which could complicate study outcomes.

**Age**  
From **18 years** old to **40 years** old

**Gender**  
Male

**Phase**  
1

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **45**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, participants are randomly assigned to two groups: the intervention group (receiving creatine) and the control group (receiving a placebo). To ensure accuracy and reliability in this process, standard randomization methods have been employed. For example, the researchers have utilized computer software to generate random numbers, which determines the group assignment for each participant. These methods guarantee that the allocation of participants to groups is entirely random, with no bias or influence from external factors. In this study, no quasi-

random methods, such as assignment based on birth date, odd or even numbers, or any predetermined pattern, have been used. Such methods are considered non-random allocation and do not provide the same level of validity as full randomization. Overall, to maintain scientific rigor and minimize bias, the researchers have ensured that the assignment of participants to the intervention and control groups is carried out completely randomly, using validated randomization methods.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, blinding has been carefully designed to ensure that several groups involved are unaware of the allocation to the intervention and control groups:  
Participants: The participants are unaware of whether they have been assigned to the intervention group (receiving creatine) or the control group (receiving a placebo). This blinding is achieved by using supplement and placebo capsules that are identical in appearance, with no distinguishable differences for the participants.  
Principal Investigator: The principal investigator, responsible for the overall management of the study, is also blinded to the participants' group assignments. This blinding is implemented to prevent any bias in the interpretation and analysis of the data. These blinding procedures are crucial for maintaining the scientific integrity of the study and minimizing any potential bias throughout the research process. It is important to note that participants are fully informed about their involvement in the study, and adequate information has been provided to them. The lack of awareness regarding group allocation does not imply that participants are unaware of their participation in the study, and it does not in any way violate ethical research principles.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**  
1

**Ethics committee**  
**Name of ethics committee**  
Ethics Committee/Research Ethics Working Group of the Schools of Health, Nutrition, and Food Science  
**Street address**  
Karimkhan Zand Boulevard, Shiraz, Fars  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
07132305410  
**Approval date**

2024-01-14, 1402/10/24

**Ethics committee reference number**

IR.SUMS.SCHEANUT.REC.1403.021

**Health conditions studied**

1

**Description of health condition studied**

Hairloss

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Change in hair density based on counting the number of hair strands in a specific area of the scalp, using standard imaging techniques at different time points (before the intervention and three months after the intervention).

**Timepoint**

before the intervention and three months after the intervention

**Method of measurement**

using standard imaging techniques

**Secondary outcomes**

1

**Description**

Changes in serum hormone levels: Measurement of changes in testosterone, dihydrotestosterone (DHT), and other related hormones at different time points throughout the study. Hair loss rate: Assessment of the extent of hair loss using standard imaging techniques in specific areas of the scalp, conducted at various time intervals before and after the intervention.

**Timepoint**

After 3 months

**Method of measurement**

Use of standard imaging techniques/blood tests

**Intervention groups**

1

**Description**

Intervention group: Participants in the intervention group will receive a daily standard dose of creatine supplement. This dosage is determined based on common and safe guidelines for creatine consumption in athletes.

**Category**

Lifestyle

2

**Description**

Control group: Participants in the control group will receive a daily standard dose of a placebo supplement containing 5 grams of maltodextrin.

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

the Iran Center for Dermatology and Hair Research.

**Full name of responsible person**

Mohammadyasin Lak

**Street address**

Shohada Tajrish Hospital, Shahr-dari Street, Qods Square, Tajrish, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2274 1507

**Email**

src@sbmu.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

the Iran Center for Dermatology and Hair Research.

**Full name of responsible person**

Mohammadyasin Lak

**Street address**

Shohada Tajrish Hospital, Shahr-dari Street, Qods Square, Tajrish, Tehran, Iran

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**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 21 2274 1507

**Email**

src@sbmu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

the Iran Center for Dermatology and Hair Research.

**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**  
Other

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
the Iran Center for Dermatology and Hair Research.  
**Full name of responsible person**  
Mohammadyasin Lak  
**Position**  
Student  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Physiology  
**Street address**  
Unit 4, No. 15, Corner of 3rd Alley, Shahrara,  
Sattarkhan, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1443793120  
**Phone**  
+98 21 6690 1745  
**Email**  
yasinlakifbb@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Sport sciences research institute  
**Full name of responsible person**  
Mohammadyasin Lak  
**Position**  
student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Physiology  
**Street address**  
Unit 4, No. 15, Corner of 3rd Alley, Shahrara,  
Sattarkhan, Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1443793113  
**Phone**

+98 21 6690 1745  
**Email**  
yasinlakifbb@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Sport sciences research institute  
**Full name of responsible person**  
Mohammadyasin Lak  
**Position**  
Student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Physiology  
**Street address**  
No. 3, 5th Alley, Mir Emad Street, Motahari Street,  
Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1587958711  
**Phone**  
+98 21 8874 7836  
**Email**  
yasinlakifbb@gmail.com

## 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

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available

### Title and more details about the data/document

Individual Participant Data: Description: Individual participant data, including demographic information, hormonal test results, and hair loss assessments. Data Sharing Details: These data will be shared after full anonymization (removal of any personally identifiable information). Only data related to primary outcomes (such as hair density and hormonal changes) will be shared. Statistical Analysis Results: Description: Files containing statistical analysis results related to the effects of creatine supplementation on the study's primary outcomes. Data Sharing Details: These data will be shared in full and without any restrictions, making them accessible to researchers and the scientific community. Study Protocol: Description: The complete

study protocol, including methods, design, and inclusion/exclusion criteria. Data Sharing Details: This protocol will be shared after the study's completion and will be made available for use by other researchers. Reports Related to Secondary Outcomes: Description: Information and results related to secondary outcomes, such as minor changes in other health parameters. Data Sharing Details: This information will be shared selectively, based on requests from other researchers.

**When the data will become available and for how long**

After Study Completion

**To whom data/document is available**

University Professors, Researchers

**Under which criteria data/document could be used**

If it can be useful for future studies and provide guidance for them

**From where data/document is obtainable**

Send an email to Yasinlakifbb@yahoo.com

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

Send an email Formal request Receive documents

**Comments**