Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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)

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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, Shahrdari Street, Qods Square, Tajrish, Tehran, Iran

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1989934148

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

the Iran Center for Dermatology and Hair Research.

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

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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