Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of creatine supplementation on improving patient-reported functional outcomes after THA hip arthroplasty: A randomized, double-blind clinical trial

Protocol summary

Study aim

Investigating the effect of creatine supplementation on improving patient-reported functional outcomes after THA hip arthroplasty: A randomized, double-blind clinical trial

Design

60 patients are selected and divided into two groups. The division of patients into exposure and control groups is done with the help of randomization software in a ratio of 1:1, and the allocation remains hidden from the researchers and the participating patients until the end of the study.

Settings and conduct

This study is a randomized, double-blind clinical trial conducted in the Orthopedic Department of Imam Khomeini Hospital among patients undergoing total hip arthroplasty. The aim is to evaluate the effect of oral creatine supplementation on postoperative functional recovery. Participants are randomly assigned to either the creatine or placebo group after providing written informed consent.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 45 to 75 Both sexes Candidate for primary unilateral total hip replacement Exclusion criteria: Any previous history of hip surgery A history of cardiovascular, hepatic, endocrine, hematological, respiratory, or peripheral vascular disease A history of kidney disease or GFR less than 30 mL/min Active cancer A history of use of corticosteroids or anabolic steroids in the past 2 weeks

Intervention groups

The intervention group consists of post-op patients who have undergone THA and, in addition to standard medications (cephalexin, acetaminophen, and NSAIDs), receive a creatine supplement powder at a dose of 5 grams once daily for 6 weeks after surgery. The control group consists of post-operative patients who have undergone total hip replacement and, in addition to standard medications, receive a placebo powder identical to the creatine at a dose of 5 grams daily for 6 weeks post-op.

Main outcome variables

Hip Abductor and Knee Extensor muscles volume

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200305046700N10**
Registration date: **2025-11-02, 1404/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-02, 1404/08/11**
Update count: **0**

Registration date

2025-11-02, 1404/08/11

Registrant information

Name

Mohammadreza Razzaghof

Name of organization / entity

Country

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-08-11, 1404/05/20

Expected recruitment end date

2029-08-10, 1408/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of creatine supplementation on improving patient-reported functional outcomes after THA hip arthroplasty: A randomized, double-blind clinical trial

Public title

Investigating the effect of creatine supplementation on patient-reported functional outcomes after hip arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People aged 45 to 75 Both sexes (male and female) Candidate for primary unilateral total hip replacement Ability to follow up for follow-up visits

Exclusion criteria:

Any previous history of hip surgery Severe endocrine disorders A history of cardiovascular, hepatic, hematological, respiratory, or peripheral vascular disease A history of kidney disease or CKD with a GFR less than 30 mL/min Active cancer A history of use of corticosteroids or anabolic steroids in the past 2 weeks

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization and Allocation Concealment A 1:1 randomization sequence was generated using a random number generator in a statistical software program to assign participants to either the creatine supplement or placebo group. To maintain balance in group sizes, random block sizes of 4 and 6 were used. The final allocation sequence was generated and kept by an independent statistician who was not involved in participant recruitment or assessment. Participant allocation was implemented using sequentially numbered, sealed, opaque envelopes to ensure allocation concealment, so that individuals involved in participant enrollment and assessment had no prior knowledge of the randomization sequence or group assignments. Blinding The study was conducted in a double-blind manner (participant and assessor). Neither the participants nor the outcome assessors were aware of the assigned interventions (creatine or placebo). The supplement and placebo were identical in appearance, packaging, and labeling. Only the research pharmacist, who had access to the randomization code, was authorized to break the code in emergency situations. Any code breaks were documented and will be reported in the final study report.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient and their clinical caregiver are specifically blinded. One group receives standard postoperative medications plus a creatine-like placebo for 6 weeks, and the other group receives 5 grams of creatine supplement daily for 6 weeks after surgery in addition to standard medications (cephalexin, acetaminophen, and NSAIDs).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Central building, Office of Vice-President for Research Affairs, Keshavarz Blvd., Tehran , Iran.

City

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Province

Tehran

Postal code

1416634793

Approval date

2025-05-20, 1404/02/30

Ethics committee reference number

IR.TUMS.IKHC.REC.1404.117

Health conditions studied

1

Description of health condition studied

Hip Osteoarthritis

ICD-10 code

M16

ICD-10 code description

Osteoarthritis of hip

Primary outcomes

1

Description
Hip Abductor muscles volume
Timepoint
before intervention, 1 month post intervention, 3 months post intervention
Method of measurement
Ultrasonography

2

Description
Knee Extensor muscles volume
Timepoint
before intervention, 1 month post intervention, 3 months post intervention
Method of measurement
Ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In addition to the usual medications (cephalexin, acetaminophen, and NSAIDs), this group received creatine supplement powder (manufactured by Karen Company) at a dose of 5 grams once a day for 6 weeks (42 days) after surgery.
Category
Treatment - Drugs

2

Description
Control group: This group receives 5 grams of placebo powder (manufactured by Karen Company) daily, along with standard medications (cephalexin, acetaminophen, and NSAIDs), for 6 weeks after surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Joint Reconstruction Research Center/ Tehran University of Medical Sciences
Full name of responsible person
Seyed Mohammad Javad Mortazavi
Street address
Joint Reconstruction Research Center, Imam Khomeini Hospital Complex, East Baqerkhan Street, North Chamran Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Email
vcr@tums.ac.ir
Web page address
https://vcr.tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
80
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
Tehran University of Medical Sciences
Full name of responsible person

Ali Mazidi

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Nelson Mandela Boulevard (Africa), No. 3, West Nahid Street

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info@karenpharma.com

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences

Proportion provided by this source
20

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr. Mohammadreza Razzaghof

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to

make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available