Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Ascorbic Acid (Vitamin C) on Functional Recovery and Pain relief Following Open Rotator Cuff Repair: A Randomized Clinical Tria

Protocol summary

Study aim

1.To provide scientific evidence regarding the impact of ascorbic acid supplementation on functional recovery in patients following rotator cuff repair surgery.

Design

A parallel-group, double-blind, randomized clinical trial will be conducted on 64 patients using block randomization via the software available at randomizer.org

Settings and conduct

This study will be conducted at Firouzgar Hospital among patients diagnosed with full-thickness rotator cuff tears. Follow-up assessments will be performed using structured questionnaires and clinical examinations

Participants/Inclusion and exclusion criteria

Inclusion Criteria Patients aged 18 years and older undergoing open surgical repair for rotator cuff tears. Confirmation of full-thickness tear in one or more rotator cuff tendons based on preoperative MRI and intraoperative verification. Provision of written informed consent to participate in the study and commitment to scheduled postoperative follow-up. Adequate general health status to complete the standard postoperative treatment and rehabilitation process. Exclusion Criteria History of prior surgical intervention on the same shoulder Presence of neurological or muscular disorders that may affect shoulder functional outcomes . Significant concomitant injuries to other shoulder structures Pregnancy or presence of uncontrolled systemic conditions such as poorly managed diabetes mellitus or advanced renal failure.

Intervention groups

In the intervention group, an oral vitamin C supplement at a daily dose of 500 mg will be administered starting from the first postoperative day and continued for six weeks. The selected brand is Nature Made®. The control group will receive a placebo for comparative evaluation

Main outcome variables

Upper limb function Pain intensity Range of motion of the shoulder joint

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250825066991N1**
Registration date: **2025-09-23, 1404/07/01**
Registration timing: **registered_while_recruiting**

Last update: **2025-09-23, 1404/07/01**
Update count: **0**

Registration date

2025-09-23, 1404/07/01

Registrant information

Name

alireza ebadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3883 6969

Email address

ebadi.al@iums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Ascorbic Acid (Vitamin C) on Functional Recovery and Pain relief Following Open Rotator Cuff Repair: A Randomized Clinical Tria

Public title
"The effect of vitamin C on the treatment of torn rotator cuff injuries.

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients over the age of 18 undergoing open surgical repair for rotator cuff tears Confirmation of full-thickness tear in one or more rotator cuff tendons based on preoperative MRI assessment and intraoperative verification. "Provision of written informed consent to participate in the study and commitment to postoperative follow-up according to the specified schedule Adequate general health status to undergo the standard postoperative treatment and rehabilitation process

Exclusion criteria:
Shoulder Revision Surgery "Presence of neurological or muscular disorders that may affect shoulder functional outcomes (e.g., neuromuscular diseases) Presence of significant concomitant injuries to other shoulder structures (e.g., extensive glenoid labrum tear or advanced glenohumeral joint osteoarthritis) "Pregnancy or the presence of uncontrolled systemic diseases such as uncontrolled diabetes mellitus or advanced renal failure

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly assigned to either the intervention or control group using block randomization implemented through specialized software. In block randomization, a predetermined number of patients (e.g., multiples of 4 or 6) are grouped into blocks, and the allocation sequence within each block is randomly generated to ensure balanced group sizes. This method helps maintain an approximately equal number of participants in both groups throughout the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
To ensure a double-blind study design, the supplement and placebo were manufactured to be identical in appearance, taste, and packaging. Each product was labeled with a unique code rather than a name, and these codes were accessible only to the pharmacist or principal investigator. The codes remained concealed until the end of the study. Consequently, neither the patients nor the clinical team, evaluators, or statistical analysts were aware of the type of intervention administered.

Placebo
Used

Assignment
Parallel

Other design features
"In the intervention group, an oral vitamin C supplement at a daily dose of 500 mg will be administered starting from the first postoperative day and continued for six weeks. The selected brand is Nature Made®. The aim of this intervention is to enhance tendon healing and reduce the risk of re-tear, based on findings from recent studies

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the School of Medicine, Iran University of Medical Sciences.

Street address
Iran University of Medical Sciences Adjacent to Milad Tower, Hemmat Highway Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2025-08-14, 1404/05/23

Ethics committee reference number
IR.IUMS.FMD.REC.1404.329

Health conditions studied

1

Description of health condition studied
Rotator Cuff Tear

ICD-10 code
M75.12

ICD-10 code description
Complete rotator cuff tear or rupture not specified as traumatic

Primary outcomes

1

Description
Determination of the mean (± standard deviation) scores of upper limb function (QuickDASH) in the ascorbic acid intervention group and the control group.
Timepoint
Week 12 and Week 24
Method of measurement
QuickDASH Questionnaire

2

Description
Comparison of mean upper limb functional scores (QuickDASH) between the ascorbic acid intervention group and the control group
Timepoint
Week 12 and Week 24 after surgery
Method of measurement
QuickDASH Questionnaire

3

Description
etermination of the mean (± standard deviation) pain intensity scores in the ascorbic acid intervention group and the control group.
Timepoint
At weeks 2, 6, 12, and 24 following the surgery
Method of measurement
Visual Analogue Scale Questionnaire

4

Description
Comparison of the Mean Pain Intensity Between the Ascorbic Acid Group and the Control Group
Timepoint
At weeks 2, 6, 12, and 24 following the surgery
Method of measurement
Visual Analogue Scale Questionnaire

5

Description
Determination of the Mean (Standard Deviation) of Shoulder Joint Range of Motion (ROM) in the Ascorbic Acid Group and the Control Group
Timepoint
Weeks 12 and 24 following the surgery
Method of measurement
Using an instrument called a goniometer

6

Description
Comparison of the Mean Shoulder Joint Range of Motion (ROM) Between the Ascorbic Acid Group and the Control Group
Timepoint
Weeks 12 and 24 following the surgery
Method of measurement
Using an instrument called a goniometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive an oral vitamin C supplement at a daily dose of 500 mg, starting from the first day after surgery and continuing for a duration of six weeks. The selected brand for supplementation is Nature Made®.
Category
Treatment - Drugs

2

Description
Control group: The group that receives the placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
firoozgar hospital
Full name of responsible person
Alireza ebadi
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Firoozgar Hospital, Beh Afarin Street, Vali Asr Square, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Samideh Khoei
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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
Iran University of Medical Sciences

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
Iran University of Medical Sciences

Full name of responsible person
Alireza Ebadi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
No - There is not 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

Participant Data File Informed Consent Form

When the data will become available and for how long

Access to the resources will commence at the end of the Iranian calendar year 1406, corresponding approximately to March 2028.

To whom data/document is available

for all people

Under which criteria data/document could be used

All individuals requesting to review the rotator cuff data are granted access to the dataset. Permission is hereby granted for the performance of all statistical analyses on the data. Furthermore, individuals are permitted to utilize this data in their own studies, provided that proper citation and reference is made to the original publication.

From where data/document is obtainable

Iran University of Medical Sciences Research Department Adjacent to Milad Tower, Hemmat Highway Tehran, Iran Postal Code: 1449614535 Tel: (+98 21) 86701 Email: info@iums.ac.ir

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

Following correspondence with the Research Department of Iran University of Medical Sciences, access to the dataset will be granted within one business week.

Comments