

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluating the effectiveness of vitamin C intake in patients diagnosed with rotator cuff tears undergoing arthroscopic treatment

Protocol summary

Study aim

Determining the effectiveness of vitamin C intake in patients diagnosed with rotator cuff tears undergoing arthroscopic treatment

Design

This is a prospective, monocentric randomized study approved by the Kerman University of Medical Science Ethical Committee. The randomization process was carried out by year of birth: patients born in an even number year received postoperative VC supplementation at a dose of 500 mg per day orally for 45 days (VC+ group) and patients born in an odd number year received no supplementation (VC-group).

Settings and conduct

We included all patients who underwent arthroscopic a primary rotator cuff repair. The patients are then, divided into two groups. Preoperatively, then at 45 days, 3 months and 6 months, active mobility is measured using a goniometer. Also, the standardized shoulder evaluation form of american shoulder and elbow surgeons and the visual analogue scores preoperation and 6 months after the operation were determined. the participant and the evaluator are blinded. In this research, placebo is used and then vitamin C and the placebo are divided into two groups, A and B.

Participants/Inclusion and exclusion criteria

All patients undergoing arthroscopic treatment due to rotator cuff tendon tear in year 1402- 1403 will enter the study. The exclusion criteria were a retraction of at least one tendon superior or equal to grade 3, fatty degeneration of at least one muscle superior or equal to grade 3, an anatomically non-repairable tear, and an isolated injury of the subscapular (Ssc) tendon. Patients without a clinical and ultrasound evaluation at a minimum follow-up of 6 months were excluded.

Intervention groups

Vitamin C + group in which they receive vitamin C supplement 500mg per day, oral, for 45 days

Main outcome variables

Pain; Rotator Cuff tendon range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231021059783N1**

Registration date: **2023-11-19, 1402/08/28**

Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**

Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Ghazal Ejlali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3631 0312

Email address

gh.ejlali@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-25, 1402/10/04

Expected recruitment end date

2024-04-23, 1403/02/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty
Scientific title
Evaluating the effectiveness of vitamin C intake in patients diagnosed with rotator cuff tears undergoing arthroscopic treatment
Public title
Evaluating the effectiveness of vitamin C intake in patients diagnosed with rotator cuff tears undergoing arthroscopic treatment
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients undergoing arthroscopic treatment due to rotator cuff tendon tear in year 1402- 1403 after having signed the consent form will enter the study
Exclusion criteria:
A retraction of at least one tendon superior or equal to grade 3 Fatty degeneration of at least one muscle superior or equal to grade 3 An anatomically non-repairable tear An isolated injury of the subscapular tendon
Age
No age limit
Gender
Both
Phase
3
Groups that have been masked
• Participant • Outcome assessor
Sample size
Target sample size: 131
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
In this research, the participant and the evaluator are blinded. In this research, placebo is used. We use a similar product in terms of color, size, flavor, scent and other characteristics similar to vitamin C. Vitamin C and the placebo are divided into two groups, A and B, and neither the participant nor the evaluator knows which group is the placebo and which is vitamin C.
Placebo
Used
Assignment
Parallel
Other design features
Secondary Ids
empty
Ethics committees

<u>1</u>
Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Pardis of Medical University of Kerman, Haft Bagh Alavi Blvd. Kerman, Kerman
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2023-10-15, 1402/07/23
Ethics committee reference number
IR.KMU.AH.REC.1402.122
Health conditions studied
<u>1</u>
Description of health condition studied
Rotator Cuff tear
ICD-10 code
ICD-10 code description
Primary outcomes
<u>1</u>
Description
Pain
Timepoint
Pre operation, 6 months post-operation
Method of measurement
Yes-No questions based on American Shoulder and Elbow Surgeons questionnaire and Visual Analogue Scale
<u>2</u>
Description
Rotator Cuff tendon range of motion
Timepoint
Pre operation, 45 days post-operation, 3 months post-operation, 6 months post-operation
Method of measurement
Based on American Shoulder and Elbow Surgeons questionnaire and Goniometry
Secondary outcomes
empty
Intervention groups
<u>1</u>
Description
Intervention group: Vitamin C + group in which they

recieve vitamin c supplement 500mg per day, oral, for 45 days

Category

Treatment - Drugs

2

Description

Control group: Vitamin C - group in which they wont recieve any kind of supplement

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Hospital

Full name of responsible person

Ghazal Ejlali

Street address

Shafa Hospital, Kowsar Blvd. Kerman, Iran

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2

Recruitment center

Name of recruitment center

Shahid Bamonar Hospital

Full name of responsible person

Ghazal Ejlali

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Shahid Bamonar Hospital, Gharani St. Kerman, Iran

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3

Recruitment center

Name of recruitment center

Razieh Firooz Hospital

Full name of responsible person

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Street address

Razieh Firooz Hospital, West Motahari Hospital, Kerman, Iran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abedin Iran Pour

Street address

Ebn-e-Sina St. Jahad Blvd. Kerman, Iran

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Grant name

Grant code / Reference number

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

No

Title of funding source

Personal

Proportion provided by this source

100

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Ghazal Ejlali

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

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Orthopedics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

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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