

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

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

#### Protocol summary

Pain; Rotator Cuff tendon range of motion

#### 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

#### 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

### 1

#### 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

### 1

#### Description of health condition studied

Rotator Cuff tear

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### 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

### 2

#### 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

### 1

#### 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

**City**

Kerman

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**Postal code**

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+98 34 3211 5780

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shafahospital@kmu.ac.ir

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**2**

**Recruitment center**

**Name of recruitment center**

Shahid Bahonar Hospital

**Full name of responsible person**

Ghazal Ejlali

**Street address**

Shahid Bahonar Hospital, Gharani St. Kerman, Iran

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**3**

**Recruitment center**

**Name of recruitment center**

Razieh Firooz Hospital

**Full name of responsible person**

Ghazal Ejlali

**Street address**

Razieh Firooz Hospital, West Motahari Hospital, Kerman, Iran

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info@rfhospital.ir

**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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7619813159

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+98 34 3226 3719

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VCR@KMU.AC.IR

**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**

Amir Reza Sadeghi Far

**Position**

Associate professor

**Latest degree**

Subspecialist

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Orthopedics

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**Person responsible for updating data**

**Contact**

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Kerman University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

General Practitioner

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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