

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Assessment of oral Co enzyme Q10 effect on the outcomes in adults patients with Distal Radius fracture

Protocol summary

Study aim

Determining and comparing the effect of oral coenzyme Q-10 consumption on the results of treatment of adult distal radius fractures

Design

Double-blind clinical trial study

Settings and conduct

Single blind clinical trial study will be performed on patients referred to Imam Khomeini Hospital in the age range of 18 to 40 years old. Gender opinion should be equal in both groups. In the intervention group, patients will receive 100 mg of Q-10 daily for 8 weeks, and in the control group, patients will not receive Q-10. This group will receive a placebo. Then, in the postoperative visits in weeks 4 and 8, the radiographic findings of the fusion will be examined. The DASH questionnaire will be used to evaluate the patient's function, the VAS score will be used to evaluate the pain, and the dynamometer will be used to evaluate the grip strength of the hand. And the data will be recorded. Performance is expressed and calculated based on the DASH questionnaire and this questionnaire consists of 30 questions, each of which receives between one point and five points based on the severity of the disorder, and the total score will be calculated and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Distal radius fracture with metaphysical instability according to AO criteria group C1, C2, A3 and A2 or an intra-articular fracture line and displacement in an adult who has been treated by skin pinning. Exclusion criteria: Patients with displaced intra-articular fractures requiring open surgery. People with underlying disease or taking drugs that interfere with bone metabolism

Intervention groups

Intervention group of patients 100 mg Q-10 daily for 8 weeks. Control group: placebo.

Main outcome variables

Union speed; grip strength; function; pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211228053554N1**

Registration date: **2022-03-22, 1401/01/02**

Registration timing: **prospective**

Last update: **2022-03-22, 1401/01/02**

Update count: **0**

Registration date

2022-03-22, 1401/01/02

Registrant information

Name

siyamak kazemisofi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 9538

Email address

kazemisofi.s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-21, 1401/03/31

Expected recruitment end date

2023-02-19, 1401/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of oral Co enzyme Q10 effect on the outcomes in adults patients with Distal Radius fracture

Public title
Assessment of oral Co enzyme Q10 effect on the outcomes in adults patients with Distal Radius fracture

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Adults (age 18 to 40 years old) with distal radius fracture
Exclusion criteria:
Patients with intra-articular fractures who require open surgery

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients will be randomly divided into two groups of treatment (100 mg Q-10 daily for 8 weeks) and control (placebo of neutral drug) with random allocation software (Random Allocation software).

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be performed by double-blind method (patients and physicians' treatment team). After a distal radius fracture with metaphysical instability according to the AO criteria of groups C1, C2, A3, and A2, or an intra-articular fracture line and displacement in an adult who has been treated by skin pinning by a specialist Orthopedics It was found that participants will be referred to a secretary to receive medication or placebo and will deliver them (medication or placebo) in two groups of patients.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of Medical Sciences

Street address

Imam Khomeini University Hospital-Ershad AVE-
Modarres Blvd- Urmia-IRAN

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Urmia

Province

West Azarbaijan

Postal code

5715789397

Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.UMSU.REC.1400.19

Health conditions studied

1

Description of health condition studied

Adult distal radius fractures

ICD-10 code

S52.50

ICD-10 code description

Adult distal radius fractures

Primary outcomes

1

Description

Duration of the distal radius fracture union

Timepoint

Before prescribing supplements and in weeks 4 and 8

Method of measurement

Radiography

2

Description

Hand grip strength

Timepoint

Before prescribing supplements and in weeks 4 and 8

Method of measurement

Dynamometer

3

Description

Intensity of pain

Timepoint

Before prescribing supplements and in weeks 4 and 8

Method of measurement

VAS pain score

4

Description

Patient performance

Timepoint

Before prescribing supplements and in weeks 4 and 8

Method of measurement

DASH performance questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, patients will receive 100 mg of Q-10 daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: patients receiving(placebo of neutral drug)for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini University Hospital

Full name of responsible person

Dr. Siamak Kazemi Sufi

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Imam Khomeini University Hospital- Ershad Ave.-
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

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Resalat Boulevard, Emergency Alley

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Web page address

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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

Oroumia 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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Siamak Kazemi Sufi

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