Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of combined dietary supplementation of protein and creatine on outcomes and acceleration of postoperative recovery in patients with peritrochantic fracture: A double-blind interventional esoteric study

Protocol summary

Study aim

Finding a better treatment and a more effective method in reducing the rate of postoperative hospitalization, readmission rate due to complications associated with peritrochantic fracture, mortality rate 30 days after surgery, one-year mortality rate and the mentioned complications.

Design

Two groups including control and intervention; each 45 participants; randomized with table

Settings and conduct

Ninety patients with peritrochantric fracture referred to Sina and Imam Khomeini Hospital in Tehran will be collected and complementary-placebo drug envelopes will be given to patients for up to 30 days. The study is randomized and triple blind includes researcher and patient and pharmaceutical company.

Participants/Inclusion and exclusion criteria

Inclusion conditions: patients with intertroch fractures and femur neck and subtroch who will be referred to Sina Hospital or Imam Khomeini Hospital in Tehran. Exclusion criteria: pregnancy; under 18 years of age; renal failure

Intervention groups

90 patients with peritrochanteric fracture were randomly divided into 2 intervention and control groups of 45 people each and received drug packets containing supplements or placebo. Laboratory and demographics and complications will be collected and compared before and one month after receiving the supplement.

Main outcome variables

Lymphocyte and CRP levels, Prealbumin and vitamin D levels - Quality of life - 30-day mortality - Interval between hospitalization and surgery - Delirium - Clinical venous thrombosis

General information

Reason for update

Correcting and updating the start and end date of the trial

Acronym

ERAS

IRCT registration information

IRCT registration number: **IRCT20230127057247N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-03, 1403/11/15**
Update count: **2**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

mohammad reza donyazad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6697 0295

Email address

dr.mrdonyazad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-01, 1402/05/10

Expected recruitment end date

2024-08-01, 1403/05/11

Actual recruitment start date

2023-08-01, 1402/05/10

Actual recruitment end date

2024-08-01, 1403/05/11

Trial completion date

2024-09-01, 1403/06/11

Scientific title

Effects of combined dietary supplementation of protein and creatine on outcomes and acceleration of postoperative recovery in patients with peritrochantic fracture: A double-blind interventional esoteric study

Public title

Effects of combined dietary supplementation of protein and creatine on outcomes in patients with peritrochanter fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Femur neck fracture or intertroch fracture or subtrochantric fracture

Exclusion criteria:

Under 18 y/o Pregnancy Renal failure

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random numbers table

Blinding (investigator's opinion)

Triple blinded

Blinding description

The supplement and placebo are blinded by the manufacturer in English letters and the patient, the executor, the researcher and the manufacturer are unaware of the complete collection of the fear and its data from receiving the supplement or placebo by the patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical Science research committe ethics

Street address

6th Floor, Central Building, Tehran University of Medical Sciences, Qods Street Intersection, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1111854767

Approval date

2022-09-23, 1401/07/01

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.212

Health conditions studied

1

Description of health condition studied

Femoral neck fracture, intertroch fracture and subtroch of femoral fracture

ICD-10 code

S72.14

ICD-10 code description

Intertrochanteric fracture of femur

Primary outcomes

1

Description

Nutritional level by checking blood lymphocyte level changes

Timepoint

At the time of hospitalization and a month later

Method of measurement

Request for testing at the time of hospitalization and one month later

2

Description

Nutritional level by checking changes in blood albumin level

Timepoint

At the time of hospitalization and a month later

Method of measurement

Request for testing at the time of hospitalization and one month later

3

Description

Nutritional level by checking changes in blood CRP level

Timepoint

At the time of hospitalization and a month later

Method of measurement

Request for testing at the time of hospitalization and one month later

4

Description

Changes in quality of life and the ability to perform daily activities and walk

Timepoint

At the time of hospitalization and a month later

Method of measurement

Parker questionnaire

5

Description

30-day mortality

Timepoint

30 days after surgery

Method of measurement

questionnaire

6

Description

Time interval between hospitalization and surgery

Timepoint

Hospitalization day and surgery day

Method of measurement

questionnaire

7

Description

Complications occurred for the patient including delirium and clinical venous thrombosis

Timepoint

In 30 days after surgery

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: including patients with pretrochanteric fractures (femoral neck, intertrochanteric and subtrochanteric) referred to Sina and Imam Khomeini Hospital in Tehran, after removing excluded cases according to the randomization table, they were divided into 2 groups. In the intervention group, after collecting demographic information and The request for tests includes cbc-crp-albumin-pre-albumin. Depending on the location and type of fracture and the clinical conditions, the patient is subjected to internal surgical fixation, and then after discharge for one month, a daily dose of 30 mg protein sachets dissolved in water, which includes He consumed creatinine, essential amino acids and protein, and after a month, the patient will be asked for the aforementioned tests and will be analyzed.

Category

Treatment - Drugs

2

Description

Control group: including patients with peritrochanteric fractures (femoral neck, intertrochanteric and subtrochanteric) referring to Sina and Imam Khomeini Hospital in Tehran, after removing excluded cases, according to the randomization table, they were divided into 2 groups, in the control group, after collecting demographic information and Request for tests including cbc-crp-albumin-pre-albumin surgery depending on the location and type of fracture and the clinical conditions of the patient is subjected to internal surgical fixation and then after discharge for a month daily placebo protein sachets of 30 mg soluble in water which includes dextrose and after a month, the patient will be asked for the above-mentioned tests and will be analyzed. The table of the amount of starting the park before and after the surgery was completed for him in a comparative manner.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina & Imam Khomeini Hospital in Tehran

Full name of responsible person

Mohammad Reza Donyazad

Street address

End of Keshavarz Boulevard, Dr. Gharib, Imam Khomeini Hospital Complex

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6119 2253

Email

Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person
Nima Bagheri
Street address
Imam Khomeini Hospital Complex, End of Keshavarz Blvd., Tehran, Iran
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1419733141
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Email
info@tpcf.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
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
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Reza Donyazad
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
the end of Keshavarz Boulevard, Dr. Gharib Street; Imam Khomeini Hospital Complex (RA) - Orthopedic Department
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dr.mrdonyazad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mohammad Reza Donyazad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Street address
the end of Keshavarz Boulevard, Dr. Gharib Street; Imam Khomeini Hospital Complex (RA) - Orthopedic Department
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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Fax
Email
dr.mrdonyazad@yahoo.com

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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable