

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Safety and Effect of Celastrol Supplementation on Rate of Union in Femur and Tibia Fracture Patients

Protocol summary

Study aim

Determining the safety and efficacy of celastrol supplementation on bone union rate, serum level of bone turnover markers and leptin.

Design

A double-blind clinical trial with parallel groups will be conducted on 70 patients who were randomly divided into intervention or control groups using SAS statistical software.

Settings and conduct

The study will be conducted on patients with femur and tibia fractures who have referred to Taleghani hospitals in Tehran. In the first phase of the study, 10 volunteers will receive 60 mg of celastrol supplements for 15 days and will be evaluated for safety and side effects over a month. Then, if there are no complications, the second phase of the study will begin. At first, by using SAS statistical software, patients will be divided into intervention group and control group. After the fixation surgery, supplementation will be done for 15 days. This study will be double blinded. Patients will be examined in post-surgery visits via bone graphs, blood tests and considered questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Closed tibia and femur fracture patients in the age range of 18-65 years with a body mass index of 18.5-35 kg/m², and blood vitamin D3 level above 12 ng/mL, who are candidates for open fixation surgery. exclusion criteria: Patients with open fractures, diabetic, history of autoimmune diseases, history of heart, liver, and kidney diseases, ISS score greater than 15.

Intervention groups

In first phase, 60 mg of celastrol solution will be daily supplemented for 14 days. In second phase, for 14 days, the intervention group will receive 60 mg of celastrol solution, the control group will receive 60 mg of liposome solution.

Main outcome variables

bone union rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220424054643N2**

Registration date: **2023-12-03, 1402/09/12**

Registration timing: **prospective**

Last update: **2023-12-03, 1402/09/12**

Update count: **0**

Registration date

2023-12-03, 1402/09/12

Registrant information

Name

faeze gouhari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2235 7483

Email address

gouhari71nutr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Safety and Effect of Celastrol Supplementation on Rate of Union in Femur and Tibia Fracture Patients

Public title
safety and effect of celastrol in bone fracture patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to cooperate and complete the informed consent form by the patient 18 to 60 years old Closed fracture of femur and tibia Body mass index ≥ 35 kg/m² SSI score between 9 and 15 Candidates for open fixation surgery Move without help from 2 months before the fracture No need for other formulas due to a special problem (kidney, lung, liver, etc.) Non malabsorption syndrome Non parathyroid gland disorders Absence of hepatic encephalopathy and liver cirrhosis Non myocardial infarction in the last month Non uncompensated congestive heart failure Non lower limb amputation Non angina symptoms Non Chest pain or shortness of breath (including severe COPD) Non kidney failure (blood creatinine lower than 1.2 mg/dL in men and 1.1 mg/dL in women/ GFR $\geq$ 90) Non Hepatic failure (AST $\leq$ 109 U/l, ALT $\leq$ 97 U/l and INR $\leq$ 1.5) No metastatic cancer No infection and sepsis No uncontrolled blood pressure No cognitive impairment (3MS score > 73) Not taking drugs that affect bone metabolism, such as calcitonin, bis-phosphonates and corticosteroids Not taking albumin solution before and after surgery Not taking supplements or formulas that strengthen the immune system including : Arginine, glutamine, vitamins C and E, selenium, zinc or omega-3 fatty acids during the last 2 weeks before the start of the intervention No allergy or lactose intolerance

Exclusion criteria:

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, patients were divided in intervention or control group using a random sequence made by SAS statistical software. In this method, a list of random numbers is created and individuals are assigned to groups according to the order of entrance at the emergency room. Random sequences were hidden using

sealed envelopes. Individuals were the randomization unit in this individual study

Blinding (investigator's opinion)
Double blinded

Blinding description
For blinding, the appearance of supplements will be completely similar and be closed. Also, Colostrum, Whey protein supplements and Maltodextrin powder are separated by a specific code, which after analyzing the results, the code for each group is determined. Researchers and physicians will not know the study groups and the type of prescription supplement.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Arabi Ave (next to Ayatollah Taleghani Hospital), Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717443

Approval date
2023-11-04, 1402/08/13

Ethics committee reference number
IR.SBMU.RETECH.REC.1402.404

Health conditions studied

1

Description of health condition studied
Femur fracture

ICD-10 code
S72

ICD-10 code description
Fracture of femur

2

Description of health condition studied
Tibia fracture

ICD-10 code
S82.1

ICD-10 code description

Fracture of upper end of tibia

3

Description of health condition studied

Tibia fracture

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

Primary outcomes

1

Description

Comparison of bone union rate

Timepoint

Bone union is assessed at 1, 3 and 6 months after surgery.

Method of measurement

Radiography

Secondary outcomes

1

Description

Comparison of serum C-reactive protein concentrations

Timepoint

This variable will be measured at baseline,14, and 90 days after surgery.

Method of measurement

Blood sample

2

Description

Comparison of interleukin-6 level

Timepoint

This variable will be measured at baseline,14, and 90 days after surgery.

Method of measurement

Blood sample

3

Description

Comparison of serum alkaline phosphatase level

Timepoint

This variable will be measured at baseline,14, and 90 days after surgery.

Method of measurement

Blood sample

4

Description

comparison of serum osteocalcin level

Timepoint

This variable will be measured at baseline,14, and 90 days after surgery.

Method of measurement

Blood sample

5

Description

comparison of complete blood count

Timepoint

This variable will be measured at baseline, 7, 14, and 90 days after surgery.

Method of measurement

Blood sample

6

Description

comparison of serum leptin level

Timepoint

This variable will be measured at baseline,14, and 90 days after surgery.

Method of measurement

Blood sample

7

Description

comparison of pain score

Timepoint

This variable will be measured at baseline,14, 60 and 90 days after surgery.

Method of measurement

visual analog scale

8

Description

Comparison of disability score

Timepoint

This variable will be measured at baseline,14, 60 and 90 days after surgery.

Method of measurement

Oswestry Disability questionnaire

9

Description

Comparison of calf circumference

Timepoint

This variable will be measured at baseline,14, 60 and 90 days after surgery.

Method of measurement

measurement

10

Description

Comparison of physical function

Timepoint

This variable will be measured at baseline,14, 60 and 90 days after surgery.

Method of measurement

Harris hip score questionnaire

11

Description

Comparison of wound infection

Timepoint

This variable will be measured at baseline,14, and 30 days after surgery.

Method of measurement

Southampton scale

12

Description

liver function tests (ALT-ALK-AST-Bilirubin- PT-INR)

Timepoint

This variable will be measured at baseline, 7,14, and 90 days after surgery.

Method of measurement

Blood sample

13

Description

renal test (BUN- Creatinine)

Timepoint

This variable will be measured at baseline, 7,14, and 90 days after surgery.

Method of measurement

Blood sample

14

Description

blood suger

Timepoint

This variable will be measured at baseline, 7,14, and 90 days after surgery.

Method of measurement

Blood sample

15

Description

electrolyte test (sodium, chloride, potassium, phosphorus, calcium)

Timepoint

This variable will be measured at baseline, 7,14, and 90 days after surgery.

Method of measurement

Blood sample

16

Description

Arterial blood gas test

Timepoint

This variable will be measured at baseline, 7,14, and 90 days after surgery.

Method of measurement

Blood sample

17

Description

urine analysis

Timepoint

This variable will be measured at baseline, 7,14, and 90 days after surgery.

Method of measurement

urine sample

18

Description

Glomerular filtration rate (GFR)

Timepoint

This variable will be measured at baseline, 7,14, and 90 days after surgery.

Method of measurement

calculation

Intervention groups

1

Description

The intervention group in the first phase of the study: this group with 10 participants will receive 60 mg of liposomal celastrol solution daily for 14 days.

Category

Treatment - Other

2

Description

The intervention group in the second phase of the study: this group with 30 participants will receive 60 mg of liposomal celastrol solution daily for 14 days.

Category

Treatment - Other

3

Description

The control group in the second phase of the study: this group with 30 participants will receive 60 mg of liposome solution daily for 14 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Hospital

Full name of responsible person

reza zandi

Street address

Ayatollah Taleghani Hospital/ arabi street/ daneshjoo Blvd/ Velenjak/ Tehran

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Phone
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Email
Reza.zandi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti University of Medical Sciences/ arabi street/ daneshjoo Blvd/ Velenjak/ Tehran
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Email
zarghi@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
50
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
faezeh gouhari
Position
researcher
Latest degree
Master
Other areas of specialty/work
Nutrition
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Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
faezeh gouhari
Position
researcher
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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