

Effects of vitamin C on pain control after hip fracture surgery

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
10/01/2026	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
12/01/2026	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
12/01/2026	Signs and Symptoms	<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study will investigate the effectiveness of perioperative and postoperative administration of ascorbic acid in controlling postoperative pain and improving functional recovery after intramedullary osteosynthesis of trochanteric fractures.

Who can participate?

Patients with pectrochanteric and intertrochanteric femoral fractures according to the AO classification at the Department of Orthopedics and Traumatology, Zenica Cantonal Hospital.

What does the study involve?

Participants will be randomly assigned to two groups: the experimental group (vitamin C group) and the control group.

The experimental or vitamin C group participants will receive 1 g of oral Vitamin C administered daily for 40 days postoperatively. The control group will receive a placebo tablet of the same size, color and shape as the Vitamin C tablet, and it will also be administered for 40 days postoperatively.

A standard surgical protocol will be applied to all participants. Fracture fixation will be performed using a short intramedullary nail or a third-generation Gamma nail (Supernail GT, Lima Corporate, Italy). The surgical procedure will be performed under general endotracheal anesthesia.

What are the possible benefits and risks of participating?

Benefits of participation in the study:

You will not directly benefit from participating in this study; however, your data may help improve understanding of the effects of ascorbic acid on postoperative analgesia and functional recovery.

Risks of participation in the study:

The risks are consistent with the standard treatment normally applied and explained to hospitalized patients. There are no additional risks for patients participating in the study compared to those treated using conventional methods.

Where is the study run from?

Zenica Cantonal Hospital, Bosnia and Herzegovina.

When is the study starting and how long is it expected to run for?

July 2023 to October 2025

Who is funding the study?

Investigator initiated and funded.

Who is the main contact?

Dr Mirza Sivro, Principal Investigator, mirzars4@gmail.com, ortopedija@kbze.ba

Contact information

Type(s)

Scientific, Principal investigator, Public

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Study information

Scientific Title

The influence of vitamin C on postoperative pain in patients with trochanteric femur fracture

Study objectives

The aim of this study was to evaluate the effect of oral vitamin C supplementation on postoperative pain severity in patients with trochanteric femur fractures treated with intramedullary nailing.

Ethics approval required

Ethics approval required

Ethics approval(s)

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Single

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Pain control in patients after hip fracture surgery.

Interventions

This prospective, single-blinded, randomized, placebo-controlled study will include 70 patients who will be surgically treated at the Department of Orthopedics and Traumatology, Cantonal Hospital Zenica, Bosnia and Herzegovina.

After checking the inclusion and exclusion criteria, patients will be randomly assigned to either the vitamin C group or the control group using a random number generator (www.randomizer.org), with each group comprising 35 patients. Participants will be blinded to group allocation as well as to the type of drug administration. Patients in the vitamin C group will receive 1 g of oral vitamin C daily in the form of two 500 mg vitamin C tablets in morning and evening doses for 40 days postoperatively. Patients in the control group will receive placebo tablets with the same size, color and shape as patients in the vitamin C group, two times daily for 40 days postoperatively. Compliance will be checked through specially designed medication log sheets during postoperative follow-ups, with a satisfactory level of 80%.

All surgeries will be performed under general anesthesia. A short cephalomedullary nail of the third generation will be used for osteosynthesis in all cases. First-generation cephalosporin will be used for antibiotic prophylaxis, and enoxaparin at a dose of 40 mg once daily, administered subcutaneously, will be used for thromboprophylaxis for 35 days postoperatively.

Baseline characteristics of patients will be noted in each group. On the second postoperative day, the drain will be removed and a control X-ray will be taken. Further X-ray controls will be performed at 6 and 12 weeks after the operation. Postoperative consultations will be performed at 2, 6 and 12 weeks when complications and side effects of vitamin C will be noted. Pain severity will be assessed using the 10-cm Visual Analogue Scale (VAS), ranging from 0 ("no pain") to 10 ("worst pain possible"), on the second postoperative day, and at 2, 6 and 12 weeks postoperatively. Assessment of VAS will be performed by the principal investigator after

providing written instructions on the process to the participants.

Functional outcome will be assessed through the Harris Hip Score (HHS) at postoperative 6 and 12 weeks. All patients will follow the same standardized rehabilitation protocol after discharge.

Intervention Type

Supplement

Primary outcome(s)

1. Pain severity measured using the Visual Analogue Scale (VAS) at 2 days, 2, 6, and 12 weeks postoperatively

Key secondary outcome(s)

1. Functional outcome measured using the Harris Hip Score (HHS) at 6 and 12 weeks postoperatively

Completion date

30/10/2025

Eligibility

Key inclusion criteria

1. AO-classified trochanteric fractures (types 31.A1, A2, A3)
2. Age ≥ 18 years
3. Injury within two weeks
4. Approval to participate in the study

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Upper age limit

90 years

Sex

All

Total final enrolment

70

Key exclusion criteria

1. Prior hip surgery
2. Polytrauma
3. Diabetes
4. Previous limb amputation
5. Renal insufficiency

6. Cardiorespiratory compromise
7. Coagulation disorders
8. Malignancy
9. Pathologic fractures
10. Contraindications to surgery
11. Medication allergies
12. Neurological deficits
13. Refusal to participate in the study

Date of first enrolment

01/07/2023

Date of final enrolment

06/03/2025

Locations

Countries of recruitment

Bosnia and Herzegovina

Sponsor information

Organisation

Cantonal Hospital Zenica

Funder(s)

Funder type**Funder Name**

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Data sharing statement to be made available at a later date