Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Preventive analgesic effect of vitamin B complex in combination with fentanyl in patients undergoing fixation surgery for lower leg fractures

Protocol summary

Study aim

To evaluate the effectiveness of vitamin B complex combined with fentanyl versus fentanyl alone on pain intensity, analgesic requirement, vital signs, and incidence of postoperative complications in patients undergoing tibial fracture fixation surgery.

Design

Randomised, double-blind, parallel group clinical trial with a control group, phase 2, conducted on 40 patients. Participants will be randomly assigned to two groups using the RAND function in Microsoft Excel. Data collection will be performed by a blinded assessor unaware of group allocation.

Settings and conduct

The study is conducted at Shahid Mohammadi Hospital, Bandar Abbas. Eligible patients are randomly assigned to receive either vitamin B complex or normal saline before surgery. General anesthesia and fentanyl are administered equally. Data are collected by a blinded assessor. Both patients and assessors are blinded to group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 65 years with ASA physical status I or II undergoing elective tibial fracture fixation surgery. Exclusion criteria: Emergency cases; allergy to vitamin B complex; history of analgesic use; cardiac, hepatic or renal failure; hemodynamic instability; multiple fractures.

Intervention groups

Intervention group: Intramuscular injection of 2 ml vitamin B complex (Becovit) prior to tibial fracture fixation surgery, combined with general anesthesia and fentanyl. Control group: Administration of normal saline with equivalent volume instead of vitamin B complex, combined with general anesthesia and fentanyl.

Main outcome variables

Pain intensity (VAS) at 1, 6, 12, and 24 hours post-op; analgesic need at same intervals; systolic and diastolic blood pressure at 0, 15, 30, and 60 minutes in recovery; heart rate at same intervals; incidence of shivering, nausea, and vomiting at 1, 6, 12, and 24 hours post-op.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250421065424N1**
Registration date: **2025-09-08, 1404/06/17**
Registration timing: **prospective**

Last update: **2025-09-08, 1404/06/17**
Update count: **0**

Registration date

2025-09-08, 1404/06/17

Registrant information

Name

Fatemeh Jamalizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3368 0510

Email address

fjamali351@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Preventive analgesic effect of vitamin B complex in combination with fentanyl in patients undergoing fixation surgery for lower leg fractures

Public title
Effect of B complex in analgesia of orthopedic patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18 to 65 with ASA I-II, who were candidates for elective orthopedic surgery for fracture fixation of the tibia, were included.

Exclusion criteria:
emergency cases those allergic to vitamin B complex those with a history of analgesic use drug addicts patients with cardiac/hepatic/renal failure hemodynamically unstable patients those with multiple fractures

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this prospective study, participants will be randomly assigned to either the intervention or control group using block randomization. The unit of randomization is individual, meaning each participant will be independently randomized. To generate the random allocation sequence, R statistical software will be used to create blocks of varying sizes (e.g., 4 and 6), ensuring balanced group sizes throughout enrollment. If key confounding variables such as age or gender are identified, stratified randomization will be applied within each stratum to achieve balanced distribution across groups. The randomization process will be implemented using sealed, opaque envelopes, prepared by an independent third party not involved in participant recruitment. Each envelope will contain the group assignment code and will be opened only after the participant’s eligibility is confirmed and baseline data are recorded. This approach ensures proper allocation concealment and minimizes selection bias. No quasi-random methods (e.g., assignment based on birth date or record number) will be used in this study. All randomization steps are designed to follow rigorous standards for true random allocation.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study employed single-blinding where patients were unaware of their group assignment (vitamin B complex + fentanyl vs fentanyl + placebo). Study medications were administered in identical, unmarked syringes, and postoperative evaluations were performed by independent nurses to maintain blinding.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences

Street address
No. 1, Kamarbandi Street, Islamic Republic Boulevard, opposite County Health Center, Shahid Mohammadi Hospital, Bandar Abbas, Hormozgan Province

City
Bandar Abbas

Province
Hormozgan

Postal code
7919698981

Approval date
2025-02-12, 1403/11/24

Ethics committee reference number
IR.HUMS.REC.1403.365

Health conditions studied

1

Description of health condition studied
Tibial Fracture

ICD-10 code
S82.201A

ICD-10 code description
Unspecified fracture of shaft of right tibia, initial encounter for closed fracture

2

Description of health condition studied
Postoperative Pain

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

3

Description of health condition studied
Pain Prevention
ICD-10 code
R52
ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Pain intensity in patients undergoing lower limb fracture fixation surgery at 1, 6, 12, and 24 hours postoperatively, measured using the Visual Analogue Scale
Timepoint
At 1, 6, 12, and 24 hours after the end of surgery
Method of measurement
Visual Analogue Scale (VAS) ranging from 0 to 10

2

Description
Requirement for specific analgesic medication (pethidine) in patients undergoing lower limb fracture fixation surgery at 1, 6, 12, and 24 hours postoperatively
Timepoint
At 1, 6, 12, and 24 hours after the end of surgery
Method of measurement
Documentation of intravenous administration of 25 mg pethidine when pain intensity exceeds 3 on the Visual Analogue Scale, recorded by an anesthesiology staff member

Secondary outcomes

1

Description
Systolic blood pressure in patients undergoing lower limb fracture fixation surgery during recovery (at 0, 15, 30, and 60 minutes postoperatively)
Timepoint
At 0, 15, 30, and 60 minutes after the end of surgery in the recovery room
Method of measurement
Measurement of systolic blood pressure using non-invasive blood pressure monitor (NIBP) via operating room monitoring system

2

Description
Heart rate in patients undergoing lower limb fracture fixation surgery during recovery (at 0, 15, 30, and 60 minutes postoperatively)
Timepoint
At 0, 15, 30, and 60 minutes after the end of surgery in the recovery room
Method of measurement
Measurement of heart rate using electrocardiogram (ECG) monitoring in the operating room

3

Description
Diastolic blood pressure in patients undergoing lower limb fracture fixation surgery during recovery (at 0, 15, 30, and 60 minutes postoperatively)
Timepoint
At 0, 15, 30, and 60 minutes after the end of surgery in the recovery room
Method of measurement
Measurement of diastolic blood pressure using non-invasive blood pressure monitor (NIBP) via operating room monitoring system

Intervention groups

1

Description
Intervention group: Patients in this group receive an intramuscular injection of vitamin B complex (BECOVIT 2ml ampoule) prior to the start of surgery.The ampoule contains: 4 mg vitamin B1, 4 mg vitamin B2, 4 mg vitamin B6, 40 mg nicotinamide, and 6 mg dexpanthenol.Manufactured by Exir Pharmaceutical Company, Iran.The medication is administered once before the orthopedic surgery for lower limb fracture fixation
Category
Treatment - Drugs

2

Description
Control group:Patients in this group will receive normal saline with the same volume as the intervention group before the surgery, instead of vitamin B complex. All other procedures including premedication, induction of anesthesia, intraoperative medications, vital sign monitoring, and postoperative care will be identical to the intervention group. Pain intensity, blood pressure, heart rate, and need for rescue analgesics will be assessed and recorded at specified time intervals after surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital, Bandar Abbas
Full name of responsible person
Dr. Hashem Jari-Neshin
Street address
No. 1, Hospital St., Imam Hossein Blvd., Shahid Mohammadi Hospital, Bandar Abbas

City
Bandar Abbas
Province
Hormozgan
Postal code
7915843661
Phone
+98 76 3367 0000
Email
fjamali351@gmail.com
Web page address
https://www.hums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Fatemeh Jamalizadeh
Street address
No. 1, Central Building, Imam Hossein Blvd., Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code
7915843661
Phone
+98 917 210 3436
Email
fjamali351@gmail.com
Web page address
https://resv.hums.ac.ir
Grant name
Not applicable
Grant code / Reference number
ندارد
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bandare-abbas University of Medical Sciences
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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Fatemeh Jamalizadeh
Position
Medical Intern
Latest degree
Bachelor
Other areas of specialty/work
General Practitioner
Street address
No. 1, Hospital St., Imam Hossein Blvd., Shahid Mohammadi Hospital, Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code
7915843661
Phone
+98 76 3367 0000
Email
fjamali351@gmail.com
Web page address
https://www.hums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Hashem Jarineshin
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
No. 1, Hospital St., Imam Hossein Blvd., Payambar Azam Educational and Medical Complex, Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code
7915843661
Phone
+98 76 3334 5009
Email
hjarineshin@yahoo.com
Web page address
https://www.hums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person

Hashem Jarineshin

Position
Professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
No. 1, Hospital St., Imam Hossein Blvd., Payambar Azam Educational and Medical Complex, Bandar Abbas

City
Bandar Abbas

Province
Hormozgan

Postal code
7915843661

Phone
+98 76 3334 5009

Email
anrc.hums@gmail.com

Web page address
https://www.hums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
De-identified individual participant data (IPD), study protocol, informed consent form, statistical analysis plan, analysis codes, clinical study report, and data dictionary will be shared after study completion. The shared data will include key outcome variables and demographic information, with all personal identifiers removed.

When the data will become available and for how long
Access to the data and documents will begin 6 months after the publication of the main study results and will remain available for 5 years.

To whom data/document is available
Academic researchers, members of recognized research institutions, and professionals in the pharmaceutical and healthcare industries with a defined scientific purpose may request access.

Under which criteria data/document could be used
Data may only be used for research and scientific analysis purposes. Applicants must submit a research proposal and sign a data use agreement ensuring ethical compliance and confidentiality. Commercial use of the data is not permitted.

From where data/document is obtainable
Requests should be directed to the corresponding author, Dr. Jerry Neshin. Address: Islamic Republic Boulevard, Shahid Mohammadi Hospital, 5-Story Building, First Floor, Anesthesiology Research Center Phone: +98 76 3334 3862 Email: anrc.hums@gmail.com

What processes are involved for a request to access data/document
Upon receiving a request, the ethics committee and research team will review it within 2 weeks. If approved, a data use agreement will be sent. Once signed, the data will be shared within another 2 weeks. The entire process takes approximately 4 weeks.

Comments
For further information or to request additional documents, please contact the corresponding author via email.