

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of dexmedetomidine infusion on N-terminal pro-B-type natriuretic peptide level in patients with femoral shaft fractures under general anesthesia

Protocol summary

Summary

Objectives: The aim of this study is to determine the effects of dexmedetomidine on NT-pro-BNP levels and hemodynamic parameters of patients with femoral shaft fractures who candidate for elective surgery under general anesthesia. **Design:** In a double blind clinical trial study, 50 patients who candidate for femoral shaft fracture elective surgery will be enrolled. They will be divided randomly in two groups. **Setting and conduct:** This study will be conducted in anesthesiology department of Imam Hosein Hospital, Tehran, Iran. **Participants including major eligibility criteria:** 15-55 years old patients with ASA Class I, II will be enrolled. **Patients with positive history of any cardiac or hepatic problem; addiction to any specific drug; using anti hypertensive, psychiatric, agonist or antagonist α -2 receptor agents; basal heart rate less than 60/min; pregnant patient; patients who had blood loss of more than 1 liter during surgery; patients for whom the time of operation took more than 3 hours will be excluded.** **Intervention:** In the dexmedetomidine group 0.5 μ g/kg/h of this drug will be infused during the time of operation. In the control group the same volume of 0.9% sodium chloride will be infused. Two blood samples were taken before induction of anesthesia and 24 hours after operation for NT-pro-BNP level assessment. **Main outcome measures:** NT-pro-BNP levels before and after surgery will be compared. Trend of change in SBP, DBP, and PR between the two groups will also be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511279593N2**

Registration date: **2015-12-27, 1394/10/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-27, 1394/10/06

Registrant information

Name

Elham Memary

Name of organization / entity

Shahid Beheshti University

Country

Iran (Islamic Republic of)

Phone

+98 21 7755 8082

Email address

drmemory@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-09-23, 1393/07/01

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of dexmedetomidine infusion on N-terminal pro-B-type natriuretic peptide level in patients with femoral shaft fractures under general anesthesia

Public title

Effect of dexmedetomidine infusion on N-terminal pro-B-

type natriuretic peptide level

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Patients with femoral shaft fracture who were candidates for elective surgery under general anesthesia; between 15 and 55 years; ASA Class I, II
Exclusion criteria: positive history of any cardiac or hepatic problem; addiction to any specific drug; using anti hypertensive, psychiatric, agonist or antagonist α -2 receptor agents; basal heart rate less than 60/min; pregnant patient; patients who had blood loss of more than 1 liter during surgery; patients for whom the time of operation took more than 3 hours

Age

From **15 years** old to **55 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research

Street address

Shahid Beheshti University of Medical Sciences

City

Tehran

Postal code

Approval date

2014-06-18, 1393/03/28

Ethics committee reference number

0400/2044

Health conditions studied

1

Description of health condition studied

Fracture of femoral shaft

ICD-10 code

S72.3

ICD-10 code description

Fracture of shaft of femur

Primary outcomes

1

Description

NT pro BNP

Timepoint

before induction and 24 hours after surgery

Method of measurement

blood level

Secondary outcomes

1

Description

systolic blood pressure

Timepoint

every 30 min from induction until end of surgery

Method of measurement

based on mmHg

2

Description

diastolic blood pressure

Timepoint

every 30 min from induction until end of surgery

Method of measurement

based on mmHg

3

Description

pulse rate

Timepoint

every 30 min from induction until end of surgery

Method of measurement

per minute

Intervention groups

1

Description

infusion of dexmedetomidine hydrochloride as 0.5 μ g/kg/h diluted in normal saline

Category

Treatment - Drugs

2

Description

same volume of normal saline as dexmedetomidine group

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hosein Hospital

Full name of responsible person
Dr. Elham Memary

Street address
Shahid Madani Street

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Elham Memari

Street address
Yemen Street

City
Tehran

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

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
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Position
Assistant Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty