

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The Effect of perineural administration of dexmedetomidine on propofol and narcotic consumption and pain intensity in the patients undergoing femoral shaft fracture surgery

Protocol summary

Summary

The goal of this study was to test whether it has any effect on pain intensity, opioid and propofol requirements when injected perineurally alone. Inclusion criteria were American Society of Anesthesiologists physical status I-II patients undergoing femoral fracture shafts surgery and their surgery duration was less than 3 hours. Exclusion criteria was allergy to an α 2-adrenergic agonist or to one of the drugs used during the study, lidocaine and fentanyl; age <18 years, renal and hepatic failure; planned intraoperative use of regional analgesia; addicted patients, treatment or consumption psychotropic medication or an opioid agonist or antagonist in the 24 hours before surgery; treatment with α 2-adrenergic agonist or antagonist; ASA physical status III-IV patients; and patient less or more than 40 and 100 kg weight, respectively. All patients with an elective femoral shaft fracture were selected in this study. The patients were randomly divided into two groups and dexmedetomidine, 100 μ g, was only injected to surround the femoral nerve in one group. In both groups total intraoperative propofol and opioid consumption (3 hours), postoperative opioid consumption, visual analogue score for pain (24 hour postoperative) and hemodynamics parameters were recorded and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204309593N1**

Registration date: **2015-11-20, 1394/08/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-20, 1394/08/29

Registrant information

Name

Elham Memary

Name of organization / entity

Shahid Beheshti University

Country

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Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-11-18, 1393/08/27

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of perineural administration of dexmedetomidine on propofol and narcotic consumption and pain intensity in the patients undergoing femoral shaft fracture surgery

Public title

The Effect of femoral block on IV anesthetic consumption and analgesia during anesthesia and post operation

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: allergy to an α 2-adrenergic agonist or to one of the drugs used during the study; atracurium; propofol; morphine; midazolam; dexmedetomidine; lidocaine and fentanyl; age <18 years, renal and hepatic failure; planned intraoperative use of regional analgesia; addicted patients, treatment or consumption psychotropic medication or an opioid agonist or antagonist in the 24 hours before surgery; treatment with α 2-adrenergic agonist or antagonist; ASA physical status III-IV patients; and patient less or more than 40 and 100 kg weight, respectively. Inclusion criteria: all patients with an elective femoral shaft fracture who had not exclusion criteria and their surgery duration was less than 3 hours were included in the study.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti commite, Beheshti University of Medical Scineces

Street address

Velenjak St

City

Tehran

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

349

Health conditions studied

1

Description of health condition studied

Femoral shaft fracture

ICD-10 code

S72.3

ICD-10 code description

Fracture of shaft of femur

Primary outcomes

1

Description

propofol consumption

Timepoint

during 3 hour intraoperative

Method of measurement

propofol consumption

2

Description

pain intensity

Timepoint

during 3 hour intraoperative and 6, 12, and 24 hour postoperative

Method of measurement

visual measurment

Secondary outcomes

1

Description

narcotic consumption

Timepoint

1, 2 and 3 hours intra-operative and 24 hour postoperative

Method of measurement

consumpted drug

Intervention groups

1

Description

In this Clinical Trail perineural administration of dexmedetomidine, 100 μ g, was done before anesthesia.

Category

Treatment - Drugs

2

Description

In the control group anesthesia was done without perineural administration of dexmedetomidine and surgery was done.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam-Hossein Hospital

Full name of responsible person

Elham Mmary

Street address

Emam-Hossein Educational and Medical Center,
Shahid Madani St

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

anesthesiology research centre,shahid beheshti
university of medical sciences

Full name of responsible person

alidabbagh

Street address

Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

anesthesiology research centre,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

Elham Memari

Position

Assistant Professor

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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