

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Clinical trial of evaluation the effect of dexmedetomidine administration during femoral neck fracture surgery on intraoperative hemodynamic factors and postoperative analgesic consumption in opium addicted patients

Protocol summary

Summary

(1) Objectives: Evaluation the effect of dexmedetomidine administration during surgery on hemodynamic factors during surgery and analgesic consumption after surgery in opium addicted patients (2) Design: This is a double blind randomized clinical trial conducted on 32 patients in Imam Hosein Hospital, Tehran, Iran. (3) Setting and conduct: Following spinal anesthesia using hyperbaric bupivacaine, the patients were divided in two groups of intervention and control. (4) Participants: 18-75 years old patients with a history of at least 6 consecutive weeks who candidate for femoral neck fracture surgery under spinal anesthesia were enrolled. Pregnant and breast feeding females, chronic pain, blood transfusion during surgery and intolerance to spinal anesthesia and need for general anesthesia were excluded. (5) Intervention: In intervention group, dexmedetomidine at rate of 0.5 µg/kg/hr and in control group normal saline with same volume was infused. At recovery, 2mg morphine was administered if visual analogue scale was more than 3. After transferring to the ward, participants were connected to patient controlled analgesia pump. (6) Main outcome measures: Vital sign changes, bleeding volume during surgery and pain onset after surgery and analgesic consumption during 24 hours after surgery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608019593N4**
Registration date: **2016-08-26, 1395/06/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-26, 1395/06/05

Registrant information

Name

Elham Memaary

Name of organization / entity

Shahid Beheshti University

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of evaluation the effect of dexmedetomidine administration during femoral neck fracture surgery on intraoperative hemodynamic factors and postoperative analgesic consumption in opium addicted patients

Public title

Evaluation the effect of dexmedetomidine administration during surgery on intraoperative hemodynamic factors and postoperative analgesic consumption in opium addicted patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18-75; Femoral neck fracture; candidate for surgery under spinal anesthesia; history of opium abuse for at least 6 weeks Exclusion criteria: Pregnancy; breast feeding; history of chronic pain; long term analgesic use; BMI>35; diabetic; ischemic heart disease; cerebral vascular attacks; hypertension; malignancy; renal failure; hepatic failure; coagulopathy; history of drug allergy; need for blood transfusion during surgery; intolerance for spinal anesthesia

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization using random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Vice chancellor for research, Shahid Beheshti University of Medical Sciences, Velenjak Street

City

Tehran

Postal code

Approval date

2016-04-20, 1395/02/01

Ethics committee reference number

IR.SBMU.MSP.REC.1395.22

Health conditions studied

1

Description of health condition studied

Femoral Neck Fracture

ICD-10 code

S72.0

ICD-10 code description

Fracture of neck of femur

Primary outcomes

1

Description

Analgesic consumption

Timepoint

Until 24 hours after surgery

Method of measurement

Calculating the total dose of analgesic consumption by the researcher

Secondary outcomes

1

Description

Pain onset

Timepoint

After finishing the surgery until first request for analgesic

Method of measurement

Time measurement by researcher based on minutes

2

Description

Hemorrhage volume

Timepoint

From the beginning until the end of surgery

Method of measurement

Calculating the bleeding volume based on milliliter by researcher

3

Description

Hemodynamic side effects

Timepoint

From drug administration until end of surgery

Method of measurement

Assessing hemodynamic changes using special monitoring device

Intervention groups

1

Description

Dexmedetomidine infusion at a rate of 0.5 µg/kg/hr during surgery in intervention group

Category

Treatment - Drugs

2

Description

Normal saline infusion with the same volume and rate of dexmedetomidine during surgery in control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hosein Hospital

Full name of responsible person

Dr. Elham Memary

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ali Ziyayi

Street address

Vice chancellor for research, 3rd floor, Medical School, Shahid Beheshti University of Medical Sciences, Velenjak, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, 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

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>