

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of adding different doses of dexamethason to fentanil in patient control analgesia after lower limb orthopedic surgeries

Protocol summary

2016-10-23, 1395/08/02

Summary

Aim: The aim of this study was to improve the quality of pain management and reduce the total fentanyl consumable in patients undergoing lower limb orthopedic surgery is spinal anesthesia. Study design: Study population, patients undergoing orthopedic surgery of the lower limbs, 102 patients in three groups of 34 patients and the control group (receiving saline intravenously cc10 slow), the first case group (receiving dexamethasone 8mg in PCA pump) and the second case group (receiving dexamethasone 16mg in PCA pump). Double-blind study and randomly divided the patients. In the study to all patients will be connected in the recovery room, intravenous pain pumps (PCA) containing 1 mg fentanyl in 100 cc saline bolus injection of 10 micrograms per cc and locking time will be 10 minutes and saline in the control group and dexamethasone in the case group Injected in the pump. Then of patients asked pain, nausea, vomiting and the need for pethidine to 24 hours and enter the pre-designed questionnaire. An inclusion criterion for this study is lower limb orthopedic surgery. This intervention study dexamethasone injection into the PCA pump in case group and normal saline in the control group. The primary outcome of pain, and secondary outcomes nausea, vomiting, pethidine requirement rate, blood pressure and heart rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071928996N1**
Registration date: **2016-10-23, 1395/08/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

Registrant information

Name

Farzad Nabipour Asri

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

f.nabipour@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of adding different doses of dexamethason to fentanil in patient control analgesia after lower limb orthopedic surgeries

Public title

The effects of different doses of dexamethasone on pain management in orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criterias: patients with age 18 to 60 years old; patients under the lower limb orthopedic surgeries; patients with ASA class 1 or 2; patient"s satisfaction exclusion criterias:allergy to dexamethasone or other corticostroides; addiction to opioeds or alchol and any drug abuse; affiction to peptic ulcer disease, renal or adrenal desease , osteopenia , osteoprosis; uncontrolled HTN; ASA class > 2; pregnancy or breast feeding; corton therapy; NSAID therapy; Patients with platelet disorders

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this randomized study was conducted as a random numbers table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Daneshgah St, Ardabil, IRAN

City

ARDABIL

Postal code

5618953141

Approval date

2016-06-13, 1395/03/24

Ethics committee reference number

IR.ARUMS.REC.1395.8

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

s82.1-s82.

ICD-10 code description

fracture of upper end of tibia , fracture of shaft of tibia , fracture of lower end of tibia

Primary outcomes

1

Description

pain

Timepoint

0 , 2 , 6 , 12 , 24 hrs after intervention

Method of measurement

VAS

Secondary outcomes

1

Description

analgesic consumption rate

Timepoint

0,2.6.12.24 hrs after intervention

Method of measurement

dosage rate

2

Description

nausea and vomiting

Timepoint

0,2,6,12,24 hrs after the intervention

Method of measurement

Postoperative nausea and vomiting score

3

Description

blood presure

Timepoint

0,2,6.12.24 hrs after the intervention

Method of measurement

manual mercuric pressure guage (mmHg)

4

Description

heart rate

Timepoint

0,2,6,12,24 hrs after the intervention

Method of measurement

Manual : bpm (Beats Per Minute)

Intervention groups

1

Description

The control group: received intravenous pain pump

contains 1 mg of fentanyl with 10 mL of saline

Category

Treatment - Drugs

2

Description

The second group: received fentanyl-containing pain pumps plus 8 mg dexamethasone. Both drugs are making in Aburaihan pharmaceutical company.

Category

Treatment - Drugs

3

Description

The second group received fentanyl-containing pain pumps plus 16 mg dexamethasone. Both drugs are making in Aburaihan pharmaceutical company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Fatemi Hospital

Full name of responsible person

Farzad Nabipour Asri MD.

Street address

Shariati Sq

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Ardabil University of Medical Sciences

Full name of responsible person

Ghodrat akhavan akbari MD.

Street address

Daneshgah St, Ardabil University of Medical Sciences

City

Ardabil

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 Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Farzad Nabipour Asri

Position

Physician / assistant anesthesia

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Ghodrat Akhavan Akbari

Position

Physician / Anesthesiologist

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Full name of responsible person

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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