Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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

2016-10-23, 1395/08/02

Registrant information

Name
Farzad Nabipour Asri
Name of organization / entity
Ardabil University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 45 3323 2520
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; uncontroled 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

Street address

Daneshgah St, Ardabil University of Medical Sciences

City

Ardabil

Postal code

5618953141

Phone

+98 45 3351 2000

Fax

+98 45 3351 8939

Email

f.nabipour@arums.ac.ir

Web page address

www.arums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Dr Fatemi Hospital

Full name of responsible person

Ghodrat Akhavan Akbari

Position

Physician / Anesthesiologist

Other areas of specialty/work

Street address

Shariati Sq, Dr Fatemi Hospital

City

Ardabil

Postal code

56147

Phone

+98 45 3323 2520

Fax

+98 45 3323 2670

Email

f.nabipour@arums.asc.irfnabipourasri@gmail.com

Web page address

www.arums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Dr. Fatemi Hospital
Full name of responsible person
Tayebe Salmanfar
Position
Physician / Anesthesiology residents
Other areas of specialty/work
Street address
Shariati Sq, Dr. Fatemi Hospital
City
Ardabil
Postal code
56147
Phone
+98 45 3323 2520
Fax
+98 45 3323 2670
Email
f.nabipour@arums.ac.ir
Web page address
www.arums.ac.ir

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