Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative study about the effect of Dexmedetomidine with Fentanyl on Post Operative Analgesia in Patient with Femur Fracture under Epidural Anesthesia

Protocol summary

Study aim
A comparative study effect of dexmedetomidine with fentanyl on postoperative analgesia in the femur fracture under epidural anaesthesia

Design
Two arm parallel-group randomised trial with double-blinded postoperative care and outcome assessment.

Settings and conduct
The study is performed in Ahvaz EmamKhomeni Hospital. All patient after monitoring and necessary measures epidural anaesthesia performed with one of the studied drugs. Double-blind study

Participants/Inclusion and exclusion criteria
Admission requirements are patient with ASA class 1and2. Age between 20and 80 years؛ Exclusion criteria are cardiovascular patients. Coagulation disorder.Spinal deformity.Infection of the site.Obesity. Allergy to the drugs. Addiction.

Intervention groups
First intervention group 23patient under epidural anaesthesia with Fentanyl. Second intervention group23patient under epidural anaesthesia with Dexmedetomidine.

Main outcome variables
Postoperative pain؛ Effect start time؛ Duration of effect؛ Repeat dose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200613047760N1**
Registration date: **2020-08-26, 1399/06/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-26, 1399/06/05**
Update count: **0**

Registration date
2020-08-26, 1399/06/05

Registrant information

Name
Seyedeh fatemeh Hosseininejad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3443 5099

Email address
hosseininejad.f@mail.ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-19, 1399/03/30

Expected recruitment end date
2020-09-21, 1399/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study about the effect of Dexmedetomidine with Fentanyl on Post Operative Analgesia in Patient with Femur Fracture under Epidural Anesthesia

Public title
Comparision of Dexmedetomidine and Fentanyl in pain control.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with ASA class 1,2 Age between 20 to 80

Exclusion criteria:

Cardiac disease patient Hematologic disease Skelletal deformity Infection of epidural site Obesity with BMI over 30 History of allergy to drugs that use Addiction

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient according to Randomise Block Perotation divided into two groups.For example for fourth block، 6block ABBA, AABB, ABAB,BABA, BBAA, BAAB exist . We placed sampling in n/4 of these blocks.Then .we use of www.sealedenevelope.com for Block Randomise

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahwaz University of Medical Science

Street address

Medical College, Jondishapoor University, Ahwaz,khuzestan

City

Ahwaz

Province

Khouzestan

Postal code

6173946831

Approval date

2020-03-15, 1398/12/25

Ethics committee reference number

IR.AJUMS.REC.1398.987

Health conditions studied

1

Description of health condition studied

Postoperative pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Postoperative analgesia with Visual analogue scale score(vas score)

Timepoint

1,2,4,6,12,24 houre after operation

Method of measurement

Visual analogue scale score (vas score)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: 150 miligram of rupivacaein 0.5 % Astrazeneca france company with 1 mg / kg dexmedetomidine exire iran company to 31 cc and injection to epidural space

Category

Treatment - Drugs

2

Description

Intervention group: 150 mg rupivacaein 0.5% Astrazeneca france company with 1 mg/ kg fentanyl abureihan iran company to 31 cc and injection to epidural space

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz Emam Khomeini Hospital

Full name of responsible person

Seyedeh Fatemeh Hosseininejad

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Seyedeh Fatemeh Hosseininejad
Street address
Ahvaz, 24 Metri Ave, Emam Khomeini Hospital, Anesthesiology Center
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Seyedeh Fatemeh Hosseininejad
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data related to project bublished in the end of project with out say the name of patient

When the data will become available and for how long

In the end of project

To whom data/document is available

Researchers in science unit

Under which criteria data/document could be used

Select better drug in practice

From where data/document is obtainable

dr seyedeh fatemeh hosseininejad
drhosseininejad@yahoo.com

What processes are involved for a request to access data/document

Send files with email to other researchers

Comments