Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative addition of Dexmedetomidini and fentanyl to intrathecal bupivacaine in orthopaedic procedure in lower limbs

Protocol summary

Summary

Neuraxial block is used in surgery and post operative pain control. Several other drugs are used to prolong the action of the spinal block such as alpha2-agonists, neostigmine, vasoconstrictions.Alpha2-agonists are like as clonidine and dexmedetomidin.Small doses of dexmedetomidin can increase the action of sensory and motor block without hemodynamic effects.in our study 78 patients in ASA1-2 within the ages of 20-65 who attended hospital for elective orthopaedic surgery in lower limbs at Rasool Akram hospital Tehran, Iran were recruited. Patents were assigned by block randomization in three groups and spinal anesthesia performed in lateral position of L4/L5 space mid line or para median method. First group received 5 micro dexmedetomidin within the volume of 0.5 cc by saline plus 2.5 cc bupivacaine0.5% and second group received 25 micro Fentanyl with 2.5 cc bupivacaine0.5%. Third group received 2.5 cc bupivacaine0.5% plus 0.5cc normal saline.Motor level function was assessed with Modified Bromage method.Time to receive T10 and above anesthesia and 2 dermatom regression and regression to S1 level was determined. Blood pressure and heart rate and SPO2 are measured every minute in first 10 minutes and then every 5 minutes. The patients, study performer and responsible person for collecting data were not aware of drug types.

General information

Acronym

Dexmedetomidini /fentanyl / intrathecal/ bupivacaine

IRCT registration information

IRCT registration number: **IRCT2017041010599N15**
Registration date: **2017-05-24, 1396/03/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-24, 1396/03/03

Registrant information

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Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-04-08, 1396/01/19

Expected recruitment end date

2018-01-02, 1396/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative addition of Dexmedetomidini and fentanyl to intrathecal bupivacaine in orthopaedic procedure in lower limbs

Public title

Comparative addition of Dexmedetomidini and fentanyl to intrathecal bupivacaine in orthopaedic procedure in lower limbs

Purpose

Treatment

Inclusion/Exclusion criteria

In our study 78 patients in ASA1-2 whit in the ages of 20-65 that attended hospital for elective orthopaedic surgery in lower limbs at Rasool Akram hospital Tehran, Iran were recruited. Exclusion criteria are: addiction; renal or hepatic failure; disrhythmic heart disease or heart block; allergy to drugs and spinal contraindications such as coagulopathy disorders, injection site infection.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients were divided to three groups. First 26 persons are located in group 1. Second 26 persons are located group 2 and third 26 persons are located in group 3. First group was put on 5 micro dexmedetomidini with2.5 cc bupivacaine 0.5%. Second group put on 25 micro Fentanyl with 2.5 cc bupivacaine 0.5% and third group put on 2.5 cc bupivacaine 0.5% only.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat high way

City

Tehran

Postal code

1449614535

Approval date

2016-04-05, 1395/01/17

Ethics committee reference number

1394.9311174025IR.IUMS.REC

Health conditions studied

1

Description of health condition studied

Regional anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Lenght of sensory block

Timepoint

Sensory level mesured every 2 minutes to higher level then mesured every 10 minutes to regresion of 2 level then every 20 minutes to regresion S1

Method of measurement

Pin prick method in midclavicular linewhith 23 gage needle

2

Description

Lengs of motor block

Timepoint

Time to Bromage 3 and regresion to bromage 0

Method of measurement

Modified bromage

3

Description

Speed of sensory block

Timepoint

Time to T10 and above dermatom

Method of measurement

Pin prick method in midclavicular line whith 23 gage needle

4

Description

Speed of motor block

Timepoint

Time to Bromage 3

Method of measurement

Modified bromage

5

Description

Sensory level

Timepoint

Sensory level mesured every 2 minutes to higher level then mesured every 10 minutes to regresion of 2 level then every 20 minutes to regresion S1

Method of measurement

Upper sensory level with pin prick method in midclavicular linewhith 23 gage needle

Secondary outcomes

1

Description
Blood presure drop
Timepoint
Before and imediatly after injection then every minute to 10 minute and then every 5 minute
Method of measurement
NIBP

2

Description
Heart rate drop
Timepoint
Before and imediatly after injection then every minute to 10 minute and then every 5 minute
Method of measurement
Manitoring system

3

Description
Need to drug
Timepoint
Before and imediatly after injection then every minute to 10 minute and then every 5 minute
Method of measurement
Registrying by anesthetic doctor or technitian

Intervention groups

1

Description
First group was put on 5 micro dexmedetomidini mixed whith normal saline up to 5cc with 2.5 cc bupivacaine 0.5%.
Category
Treatment - Drugs

2

Description
Second group put on 25 micro Fentanyl with 2.5 cc bupivacaine 0.5%
Category
Treatment - Drugs

3

Description
Control group put on 0.5 cc normal saline whith 2.5 cc bupivacaine 0.5%
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Saied Amniati
Street address
Rasool Akram Hospital, Niyayesh Ave., Satarkhan
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor of research Iran University of Medical Sciences
Full name of responsible person
Dr. Seyyed Ali Javad Mousavi
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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
Vice-Chancellor of research Iran 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
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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