

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison between intravenous Dexamethasone and Dexmedetomidine on spinal anesthesia level in opium addicted patients

Protocol summary

Study aim

Determination of the effects of Iv dexamethasone and dexmedetomidine on spinal anesthesia(SA) level in opium addicted patients

Design

Clinical Trial , Two Parallel Groups , Double-Blinded , Randomized, Phase 3, In 60 Patients

Settings and conduct

Patients will divide into two groups Dexamethasone (A) and Dexmedetomidine (B) based on a random number table. 10 min before SA, Dexamethasone will be injected in group A and Dexmedetomidine in group B. SA will be done the same for all patients . During surgery, normal saline infusion will continue for group A and dexmedetomidine infusion will continue for group B . Patients will undergo sensory and motor evaluations at intervals. The person performing SA is the same person who will assess the spinal levels and is not aware of the type of group. The patient also does not know the type of group. Another anesthesiologist who is aware of the type of drugs and the group will give the drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria : ASA class 1.2, Age 18 to 65 yrs , opium addiction , BMI <30 Exclusion criteria : Pregnancy, Dissatisfaction with SA, Coagulation disorders, neurologic disorder , Local infection in the lumbar region Sensitivity to local anesthetic

Intervention groups

Intervention in the Dexamethasone group is infusion of 8 mg Dexamethasone 10 min before SA and then infusion of 0.5 micro/Kg/hr of normal saline during surgery. Intervention in Dexmedetomidine group is infusion of 0.5 micro/Kg/hr for 10 min before SA and then infusion of the same drug at a rate of 0.5 micro/Kg/hr during surgery.

Main outcome variables

The onset of sensory block The onset of motor block Duration of motor block Time of two level regression of sensory block The first time for analgesic requirement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120430009593N15**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Elham Memary

Name of organization / entity

Shahid Beheshti University

Country

Iran (Islamic Republic of)

Phone

+98 21 7755 8082

Email address

drmemory@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-21, 1400/09/30

Expected recruitment end date

2022-12-20, 1401/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between intravenous Dexamethasone and Dexmedetomidine on spinal anesthesia level in opium addicted patients

Public title

Effect of intravenous Dexmedetomidine and Dexamethasone on spinal anesthesia in opium addicted patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with drug addiction Patients with ASA class 1,2
Patients with BMI <30 Patients aged 18 to 65 years

Exclusion criteria:

Pregnant patients Patients with dissatisfaction with spinal anesthesia Patients with coagulation disorders Patients with a history of multiple sclerosis Patients with local infection in the lumbar region Patients with allergies to local anesthetics Patients with systemic infections Patients with diabetic neuropathy Patients with bradycardia with less than 50 HR

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method : Randomization : Simple
Randomization Unit: based on patient Randomization
Tool: Random Number Table - Block stratified randomization software window version 6.0. Using this software, a random number table will be created and accordingly , the sample will be divided into two groups of 30 patients in such a way that at the beginning of each person's entry, his / her number will be matched with the table so the type of group, dexmedetomidine or dexamethasone , will be specified. The participants will not aware of the allocation of groups and won't know that the study will have two groups. The drugs will be given by first anesthesiologist who knows the groups. The person who will assess the outcome (the second anesthesiologist) also won't be aware of the group .

Blinding (investigator's opinion)

Double blinded

Blinding description

The person performing the spinal anesthesia, is the same person who will evaluate the spinal levels and does not know about the group .The patients also does not know the type of group. Another anesthesiologist who knows the type of drugs and the group will give the drugs

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of ShahidBeheshti University of Medical Sciences

Street address

Shahid Chamran Highway, Yemen St., next to Taleghani Hospital, Shahid Beheshti University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2021-07-13, 1400/04/22

Ethics committee reference number

IR.SBMU.MSP.REC.1400.202

Health conditions studied**1****Description of health condition studied**

Dexmedetomidine and Dexamethasone on Spinal Anesthesia Level in Opium Addicted Patients

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Onset of Sensory Block

Timepoint

Every 3 Minutes to 15 Minutes and then Every 5 Minutes to 30 Minutes and Every 15 Minutes to 2 Hours

Method of measurement

Pinprick Test

2**Description**

Onset of Motor Block

Timepoint

Every 3 Minutes to 15 Minutes and then Every 5 Minutes to 30 Minutes and Every 15 Minutes to 2 Hours

Method of measurement

Bromage Scale

3

Description

Duration of Motor Block

Timepoint

Every 3 Minutes to 15 Minutes and then Every 5 Minutes to 30 Minutes and Every 15 Every to 2 Hours

Method of measurement

Bromage Scale

4

Description

Regression of Two Level of Sensory Block

Timepoint

Every 3 Minutes to 15 Minutes and then Every 5 Minutes to 30 Minutes and Every 15 Minutes to 2 hours

Method of measurement

Pinprick Test

Secondary outcomes

1

Description

Total Analgesia Time

Timepoint

Every 3 Minutes to 15 Minutes and then Every 5 Minutes to 30 Minutes and Every 15 Minutes to 2 Hours

Method of measurement

According to Time with Visual Analogue Scale less than 3

2

Description

The First Time for Analgesia Requirement

Timepoint

Every 3 Minutes to 15 Minutes and then Every 5 Minutes to 30 Minutes and Every 15 Minutes to 2 Hours

Method of measurement

Analgesic Request According to VAS More than 3

Intervention groups

1

Description

Control group : Dexamethasone 8 mg 10 minutes before spinal anesthesia with bupivacaine and then normal saline infusion at a rate of 0.5 µg / kg / hr during surgery. Each Dexamethasone ampule consists of 8 mg and belongs to Alborz Drug Company

Category

Treatment - Drugs

2

Description

Intervention group : Dexmedetomidine infusion at a dose of 0.5 micrograms per kilogram of body weight for 10

minutes before spinal anesthesia and then infusion at a dose of 0.5 micrograms per kilogram of body weight. Each Dexmedetomidine vial consists of 2 c.c (200microgram)and belongs to Exir Drug company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam hossein hospital

Full name of responsible person

Elham Memary

Street address

Shahid Madani Street, Imam Hossein Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Fifth Floor, Building No. 2, Shahid Arabi St., Yemen St., Shahid Chamran Highway

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Mpajouhesh@sbmu.ac.ir

Web page address

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham Mmary

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street addressoperating room, ground floor,Imam Hossein Hospital,
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Web page address<http://www.ehmc.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham Mmary

Position

Associate professor

Latest degree

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Web page address<http://info@ehmc.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham Mmary

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Web page address<http://www.ehmc.ir>**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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/documentInformation about the main and secondary outcome
without the names of the people**When the data will become available and for how long**Start the access period immediately after printing the
results**To whom data/document is available**

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used
request data via email

From where data/document is obtainable

Send email to the scientific director of research

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

After sending an email to the scientific director of the research and stating the reason for the request, the documents will be sent within 3 months

Comments