Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of efficacy of intravenous and intratechal dexmedetomidine on perioperative shivering after spinal anesthesia

Protocol summary

Study aim
determining of efficacy of intravenous and intratechal Dexmedetomidine on perioperative shivering after spinal anesthesia

Design
this study is a double blinded randomized clinical trial which applies to 150 patients that were selected with block randomization method in three groups.

Settings and conduct
This study is conducted in the Kashan Shahid Beheshti Hospital.The patient and nurse assessor will be unaware from type of study group. In the intravenous Dexmedetomidine group, spinal anesthesia is performed with bupivacaine and sodium chloride 0.9% as placebo and intravenous Dexmedetomidine is infused. In the intrathecal Dexmedetomidine group,spinal anesthesia is performed with bupivacaine and Dexmedetomidine and sodium chloride 0.9% is infused as a placebo. In the control group, spinal anesthesia is performed with bupivacaine and sodium chloride 0.9% as placebo and sodium chloride 0.9% is infused as a placebo.

Participants/Inclusion and exclusion criteria
Patients aged 18-70 years from both sexes who are candidates for surgery in the lower abdomen or lower extremities undergo spinal anesthesia enter the study.Patients with core body temperature above 37.5 °C,pregnancy,history of allergy to the drugs used in the study,presence of contraindication of spinal anesthesia,uncontrolled thyroid disease,Parkinson's disease,unstable coronary artery disease,grade II and III cardiac blockage, severe mitral valve stenosis and surgeries requiring excessive washing with fluids (eg TURP) do not enter to study.

Intervention groups
Patients are divided in three groups:The intrathecal Dexmedetomidine group which is injected intrathecal and intravenous Dexmedetomidine group which is given intravenously and control group which is given intravenous and intrathecal placebo.

Main outcome variables
shivering; core body temperature; heart rate; systolic blood pressure; diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171014036771N1**
Registration date: **2019-01-16, 1397/10/26**
Registration timing: **prospective**

Last update: **2019-01-16, 1397/10/26**
Update count: **0**

Registration date
2019-01-16, 1397/10/26

Registrant information

Name
Hamed Pahlevani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5554 0026

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pahlavani-h@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-03-21, 1398/01/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of intravenous and intratechal dexmedetomidine on perioperative shivering after spinal anesthesia

Public title

effect of intravenous and intratechal dexmedetomidine on shivering

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-70 years/old ASA class I-II lower abdominal and lower limb surgery spinal anesthesia for surgery Duration of surgery is 30-120 minutes.

Exclusion criteria:

Core body temperature higher than 37.5 ° C Pregnancy History of allergy to the drugs used in the study Contraindications for spinal anesthesia Patient with uncontrolled thyroid disease Parkinson's Disease disautonomy Raynaud syndrome Cardiopulmonary Disease History of alcohol consumption unstable coronary artery disease heart block (degree of II and III) congestive heart failure severe mitral stenosis vasodilator drugs consumption Surgeries requiring washing with excess fluid (eg TURP).

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

in randomized blocking using 6 blocks are divided into three groups of intravenous dexmedetomidine, intrathecal and placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

After explaining the entry into the study for patients and obtaining written consent from them and implementing the randomization method,Based on designated group, researcher or the person substituting the drug or placebo is prescribed, as in the intrathecal dexmedetomidine, IV normal saline is prescribes and in the group IV Dexmedetomidine, intrathecal normal saline is prescribes, and in the control group prescribes IV and intrathecal normal saline, Without the assessor being informed of the type of prescribing and patient group, and the unaware assessor who are anesthetist nurses in the operating and recovery room, record the variables of the study

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kashan University of Medical Sciences

Street address

Hekmat 56 Ave., Ghotb Ravandi Blvd.

City

Kashan

Province

Isfehan

Postal code

8715981151

Approval date

2016-08-28, 1395/06/07

Ethics committee reference number

IR.KAUMS.REC.1395.56

Health conditions studied

1

Description of health condition studied

shivering after spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

shivering

Timepoint

During surgery every 5 minutes and during recovery every 15 minutes

Method of measurement

shivering Usta and Gozdemir scale

Secondary outcomes

1

Description

core temperature

Timepoint
Every 15 minutes from the start of surgery to the end of recovery
Method of measurement
digital tympanic thermometer

2

Description
heart rate
Timepoint
The first 15 minutes of starting surgery every 5 minutes and then until the end of recovery every 15 minutes
Method of measurement
Digital Cardiac Monitoring

3

Description
systolic blood pressure
Timepoint
The first 15 minutes of starting surgery every 5 minutes and then until the end of recovery every 15 minutes
Method of measurement
Digital Cardiac Monitoring

4

Description
diastolic blood pressure
Timepoint
The first 15 minutes of starting surgery every 5 minutes and then until the end of recovery every 15 minutes
Method of measurement
Digital Cardiac Monitoring

Intervention groups

1

Description
Intervention group: intrathecal Dexmedetomidine group spinal anesthesia with 3ml (15mg) hyperbaric bupivacaine 0.5% (Marcaine spinal 0.5% AstraZeneca) + 0.5ml Dexmedetomidine (Precedex 100µg/ml) from its diluted solution as 10µg/ml (5µg) and infused intravenous NaCl 0.9% first 1ml/kg/10min and then 0.5ml/kg/hour.
Category
Treatment - Drugs

2

Description
Intervention group: intravenous Dexmedetomidine group spinal anesthesia with 3ml (15mg) hyperbaric bupivacaine 0.5% (Marcaine spinal 0.5% AstraZeneca) + 0.5ml NaCl 0.9% and infused intravenous Dexmedetomidine (Precedex 100µg/ml) from its diluted solution as 1µg/ml first 1ml/kg/10min and then 0.5ml/kg/hour.
Category
Treatment - Drugs

3

Description
Control group: spinal anesthesia with 3ml (15mg) hyperbaric bupivacaine 0.5% (Marcaine spinal 0.5% AstraZeneca) + 0.5ml NaCl 0.9% and infused intravenous NaCl 0.9% first 1ml/kg/10min and then 0.5ml/kg/hour.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti hospital
Full name of responsible person
Hamed Pahlevani
Street address
Hekmat 56 ave., Ghotb Ravandi blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
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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
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Hamed Pahlevani

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
data can be shared after unidentifiable people.

When the data will become available and for how long
Start the access period after printing the results.

To whom data/document is available
Researchers working in academic, scientific and industrial institutions.

Under which criteria data/document could be used
Does not apply.

From where data/document is obtainable
Dr. Hamed Pahlevani- kashan- shahid beheshti hospital-

Postal code: 8715981151 pahlavani-h@kaums.ac.ir

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

After sending the request by email or post, Immediately he is contacted and After knowing the cause and purpose of data access, They will be sent immediately via e-mail (or any other method).

Comments