

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

comparison between the effect of Magnesium sulfate , dexmedetomidine and petidine on post operative shivering during general Anesthesia

Protocol summary

Study aim

comparison between the effect of Magnesium sulphate , dexmedetomidine and petidine on post operative shiverin during general Anesthesia

Design

Randomised, superiority, parallel group trial with double blinded outcome assessment ; block randomization was performed .

Settings and conduct

128 patients will randomly assigned to receive intravenous 30 mg/kg magnesium sulfate (group M= 32) , 0/5 µg/kg dexmedetomidine (dexmedetomidine group D = 32), 0/5 mg/kg pethidine (group P= 32)and distilled water(groupC= 32).

Participants/Inclusion and exclusion criteria

Inclusion Criteria : Patients in ASA I,II undergoing abdominal surgery with general anesthesia ages between 18-65 (year) No history of MAOI , TCA , Analgesic, vasoactive agents, opioid use before undergoing surgery No history of known sensitivity to Magnesium sulphate , dexmedetomidine and petidine Patient satisfaction ; Exclision Criteria : Surgery longer than 300 minutes , changing operation , extensive hemorrhage during surgery ,unstable hemodynamic during surgery

Intervention groups

. Group M: 30 mg/kg Magnesium Sulfate, Group D: 0/5 mcg/kg dexmedetomidine , Group P : 0/5 mg/kg Pethidine and Group C : normal saline

Main outcome variables

Assessment parameters includes systolic and dyastilic pressure; HR ; central temperature; peripheral temperature; sedation score; sevierity of pain and shivering ; duration of extubation ; anesthesia ; surgery; recovery ; sedation; and side effects .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190606043828N1**
Registration date: **2019-07-07, 1398/04/16**
Registration timing: **retrospective**

Last update: **2019-07-07, 1398/04/16**

Update count: **0**

Registration date

2019-07-07, 1398/04/16

Registrant information

Name

Atefeh Sharifian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3777 2315

Email address

sharifian.atefeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison between the effect of Magnesium sulfate , dexmedetomidine and petidine on post operative shivering during general Anesthesia

Public title

comparison between the effect of Magnesium sulfate , dexmedetomidine and petidine on post operative shivering during general Anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients in ASA I,II undergoing abdominal surgery with general anesthesia ages between 18-65 (year) No history of MAOI , TCA , Analgesic, vasoactive agents, opioid use before undergoing surgery No history of known sensitivity to Magnesium sulphate , dexmedetomidine and petidine Patient satisfaction

Exclusion criteria:

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo are prepared in one form and in the forme of a volume in the syringe by the researcher ; then the hemodynamic changes are monitored and recorded , so the attending , the clinical caregiver , the evaluator and the data analyser do not recognize the type of medication used for each patient . Finally the investigator deciphers the codes after data analysis .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Ethics Committee,Isfahan University of Medical Science , Hezarjarib Street , Ifahan

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2017-05-30, 1396/03/09

Ethics committee reference number

IR.MUI.REC.1396.3.978

Health conditions studied

1

Description of health condition studied

post operative shivering

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

score of postoperative shivering based on Crassly and Mahajn score

Timepoint

at the time of intering recovery room and every 15 minutes

Method of measurement

questionnaire

Secondary outcomes

1

Description

Blood pressure

Timepoint

before surgery , post intubation , during anesthesia every 15 minutes , before IV injection , at the end of anesthesia , post extubation, entering recovery room , and every 15 minutes untill 1 hour later

Method of measurement

manometer

2

Description

Heart rate

Timepoint

before surgery , post intubation , during anesthesia every 15 minutes , before IV injection , at the end of anesthesia , post extubation, entering recovery room , and every 15 minutes untill 1 hour later

Method of measurement

HR monitor

3

Description

O2 saturation

Timepoint

before surgery , post intubation , during anesthesia every 15 minutes , before IV injection , at the end of anesthesia , post extubation, entering recovery room , and every 15 minutes until 1 hour later

Method of measurement

Pulse oxymeter

4

Description

nausea and vomiting

Timepoint

before surgery , post intubation , during anesthesia every 15 minutes , before IV injection , at the end of anesthesia , post extubation, entering recovery room , and every 15 minutes until 1 hour later

Method of measurement

questionnaire

5

Description

central temperature

Timepoint

before surgery , post intubation , during anesthesia every 15 minutes , before IV injection , at the end of anesthesia , post extubation, entering recovery room , and every 15 minutes until 1 hour later

Method of measurement

thermometer

6

Description

peripheral temperature

Timepoint

before surgery , post intubation , during anesthesia every 15 minutes , before IV injection , at the end of anesthesia , post extubation, entering recovery room , and every 15 minutes until 1 hour later

Method of measurement

thermometer

Intervention groups

1

Description

Intervention group 1 : M : magnesium sulfate . Initially , personal consent is obtained from the patient . Then the patient is placed on the operating bed and standard monitoring devices are attached and vital sign is recorded .Patient undergoes general anesthesia , at the end of the surgery, while suturing the incision , 30 mg/kg magnesium sulfate is injected IV .

Category

Treatment - Drugs

2

Description

Intervention group: D : dexmedetomidine . Initially , personal consent is obtained from the patient . Then the patient is placed on the operating bed and standard monitoring devices are attached and vital sign is recorded .Patient undergoes general anesthesia , at the end of the surgery, while suturing the incision ,0/5 mcg/kg dexmedetomidine is injected IV .

Category

Treatment - Drugs

3

Description

Intervention group:P: Pethidine . Initially , personal consent is obtained from the patient . Then the patient is placed on the operating bed and standard monitoring devices are attached and vital sign is recorded .Patient undergoes general anesthesia , at the end of the surgery, while suturing the incision , 0/5 mg/kg Pethidine is injected IV .

Category

Treatment - Drugs

4

Description

Control group: C ; normal saline . Initially , personal consent is obtained from the patient . Then the patient is placed on the operating bed and standard monitoring devices are attached and vital sign is recorded .Patient undergoes general anesthesia , at the end of the surgery, while suturing the incision , normal saline is injected IV .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Mitra Jabalameli

Street address

Alzahra hospital ,Sofe Blvd , Isfahan

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jabalameli@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

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Isfahan University of Medical Science , Hezarjarib Street , Isfahan

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Atefeh Sharifian

Position

Medical student / Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

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Full name of responsible person

Seyed Taghi Hashemi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Atefeh Sharifian

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Fax**Email**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available