Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 surgury with general anesthesia ages between 18-65 (year) No history of MAOI , TCA , Analgesic, vasoactive agents, opioid use before undergoing surgury No history of known sensitivity to Magnesium sulphate , dexmedetomidine and petidine Patient satisfaction ; Exclision Criteria : Surgury longer than 300 minutes , changing operation , extensive hemorrhage during surgury ,unstable hemodynamic during surgury

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 ; surgury; 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

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Atefeh Sharifian
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Iran (Islamic Republic of)
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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 surgury with general anesthesia ages between 18-65 (year) No history of MAOI , TCA , Analgesic, vasoactive agents, opioid use before undergoing surgury 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
Isfehan
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
questionnarie

Secondary outcomes

1

Description
Blood pressure
Timepoint
before surgury , post intubation , during aneshesia 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 surgury , post intubation , during aneshesia 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 surgury , post intubation , during aneshesia 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
Palse oxymeter

4

Description
nausea and vomitting
Timepoint
before surgury , post intubation , during aneshesia 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
questionarie

5

Description
central temperature
Timepoint
before surgury , post intubation , during aneshesia 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
tymoanometer

6

Description
peripheral temperature
Timepoint
before surgury , post intubation , during aneshesia 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
thermometer

Intervention groups

1

Description
Intervention group 1 : M : magnesium sulfate . Initially , personal consent in 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 surgury, while suturing the incision , 30 mg/kg magnesium sulfate is injected IV .
Category
Treatment - Drugs

2

Description
Intervention group: D : dexmedetomidine . Initially , personal consent in 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 surgury, while suturing the incision ,0/5 mcg/kg dexmedetomidine is injected IV .
Category
Treatment - Drugs

3

Description
Intervention group:P: Pethidine . Initially , personal consent in 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 surgury, 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 in 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 surgury, 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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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Position
Medical student / Intern
Latest degree
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Person responsible for updating data

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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