Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative efficacy of different classes of drugs for prevention of shivering after general anesthesia

Protocol summary

Summary

Study Objective: To comparison of different classes of anti-shivering drug such as ketamine , Hydrocotisone, tramadol, meperidine, and magnesium sulfate for prevention of shivering after general anesthesia. Study design: randomized, double-blind, placebo-controlled trial, phase II ,single-center, the inclusion criteria: All patients undergoing elective laparotomy and general anesthesia the exclusion criteria: have history of disease that cause or affect or impair shivering and any condition that requires treatment during the study. Sample size: 40 patients for each group. intervention: drug injection. Time of intervention: during surgery . primary outcome: Effects of drugs on shivering control

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209187686N2**
Registration date: **2012-11-13, 1391/08/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-11-13, 1391/08/23

Registrant information

Name

Hesameddin Modir

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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dr.hemodir@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences,Vice chancellor for research

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy of different classes of drugs for prevention of shivering after general anesthesia

Public title

Comparative efficacy of different classes of drugs for prevention of shivering after general anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all patients undergoing elective laparotomy under general anesthesia; age between 20 to 45 years and ASA grade I or II. Exclusion criteria: history of heart disease; history of lung disease;history of thyroid disease; history of neuromuscular disorders; liver or kidney dysfunction; alcohol abuse; drug abuser; Shivering during surgery and any complications during surgery that may require medical intervention.

Age

From **20 years** old to **45 years** old

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **240**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Arak University of Medical Sciences
Street address
Alamolhoda Ave, Arak University of Medical Sciences
City
Arak
Postal code
Approval date
2012-05-21, 1391/03/01
Ethics committee reference number
91-126-1

Health conditions studied

1

Description of health condition studied
Abnormal involuntary movements
ICD-10 code
R25
ICD-10 code description
Abnormal involuntary movements Excl: specific movement disorders , stereotyped movement disorders, tic disorders

Primary outcomes

1

Description
Post Anesthetic shivering
Timepoint
0, 10 and 20 minutes after entry to recovery room
Method of measurement
Quality Grading

2

Description
Body temperator
Timepoint
0, 10 and 20 minutes after entry to recovery room
Method of measurement
Digital Termometer

Secondary outcomes

1

Description
Saturation of Arterial O2
Timepoint
Before induction of Anaesthesia
Method of measurement
Palsoximetry

2

Description
Heart rate
Timepoint
before induction of Anaesthesia
Method of measurement
cardiac Monitoring

Intervention groups

1

Description
The first group consisted of patients who receive intravenous 2 mg/ kg Hydrocortisone ten minutes before the end of surgery
Category
Treatment - Drugs

2

Description
The second group consisted of patients who received intravenous 0.5 mg/ kg ketamin 20 minutes before the end of surgery
Category
Treatment - Drugs

3

Description
The third group consisted of patients who received slow IV infusion 2 mg/ kg tramadol 30 minutes before the end of surgery
Category
Treatment - Drugs

4

Description
The fourth group consisted of patients received bolus intravenous 80 mg/ kg magnesium sulfate
Category
Treatment - Drugs

5

Description
The fifth group includes patients that received intravenous injection of 0.4 mg/ kg meperidine before the end of surgery
Category
Treatment - Drugs

6

Description
The sixth group consisted of patients that revived intravenous 10 to 15 ml/ per kg of normal saline isothermal to the operating room during surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-Asr hospital
Full name of responsible person
Dr Hesamaldin Modir
Street address
Vali-Asr hospital, Pirouzi Ave
City
Arak

2

Recruitment center
Name of recruitment center
Amiralmomenin Hospital
Full name of responsible person
Dr Hesamaldin Modir
Street address
Amiralmomenin Hospital, Basij Square
City
Arak

3

Recruitment center
Name of recruitment center
Amirkabir Hospital
Full name of responsible person
Dr Hesamaldin Modir
Street address
Amirkabir Hospital, Parastar Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences,Vice chancellor for research
Full name of responsible person
Dr Saeed Changizi Ashtiani
Street address
Arak University Of Medical Science, Basij Square
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences,Vice chancellor for research
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
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Hesamaldin Modir
Position
Anesthesiologist
Other areas of specialty/work
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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)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty