

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

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

Protocol summary

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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

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

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)

Phone

+98 86 1313 9793

Email address

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

Paloximetry

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

City

Arak

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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Position

Anesthesiologist

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Fax**Email****Web page address****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

Person responsible for updating data**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