

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of intravenous infusion of warm saline and dexamethasone in the prevention of postoperative shivering

Protocol summary

Summary

Objectives: The aim of this study was to compare one medication and one non-medication method used for controlling post operative shivering. Design: A total of 120 patients whose physical status met the criteria of American society of Anesthesiologists, were aged 20 to 50 years, underwent elective surgery (surgical operations other than laparotomy, orthopedic, ENT), and had GA were randomly divided into three groups. Setting and intervention: After general anesthesia, warm saline was applied for the patients in group 1 (n=40), 0.15 mg per kg Dexamethasone was applied for the patients in group 2 (n=40), and saline (22 to 24 C) was applied for the patients in group 3 (n=40). The tympanic temperature was evaluated pre-operatively and intra-operatively and post-operatively. Inclusion criteria for the group I and II were the followings: laparoscopic surgery under general anesthesia, surgery, ENT surgery and eye surgery, being aged 20 to 50 years, avoiding the use of corticosteroids, non-steroidal analgesics, magnesium sulfate and blood pressure medications, no fever, no addiction, normal body temperature (the temperature of 36.5 to 37.5), as well as the physical class of ASA (American Society of Anesthesiology). Exclusion criteria also included the followings: emergency surgery, blood transfusion during surgery, surgery lasting more than two hours, neuromuscular disease, low blood pressure during surgery for any reason that required more fluid intake or changed the calculation program, and taking medical and non-medical anesthetic drugs. Main outcome measures: Shivering was evaluated and recorded post-operatively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015041721806N1**

Registration date: **2015-07-21, 1394/04/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-21, 1394/04/30

Registrant information

Name

Abolfazl Abdollahpoor

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous infusion of warm saline and dexamethasone in the prevention of postoperative shivering

Public title

Comparison of intravenous infusion of warm saline and dexamethasone in the prevention of postoperative shivering

479/94

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria for the group I and II were the followings: laparoscopic surgery under general anesthesia, surgery, ENT surgery and eye surgery, being aged 20 to 50 years, avoiding the use of corticosteroids, non-steroidal analgesics, magnesium sulfate and blood pressure medications, no fever, no addiction, normal body temperature (the temperature of 36.5 to 37.5), as well as the physical class of ASA (American Society of Anesthesiology). Exclusion criteria also included the followings: emergency surgery, blood transfusion during surgery, surgery lasting more than two hours, neuromuscular disease, low blood pressure during surgery for any reason that required more fluid intake or changed the calculation program, and taking medical and non-medical anesthetic drugs.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij bolvar

City

Semnan

Postal code

Approval date

2015-03-17, 1393/12/26

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Postoperative shivering

ICD-10 code

T88.9

ICD-10 code description

Complication of surgical and medical care, unspecified

Primary outcomes

1

Description

Shivering

Timepoint

On arrival the patient to the operating room, anesthesia beginning, the end of the anesthesia, the beginning of recovery and the recovery

Method of measurement

Thermometer

Secondary outcomes

1

Description

Hemodynamics(Blood presure)

Timepoint

On arrival the patient to the operating room, anesthesia beginning, the end of the anesthesia, the beginning of recovery and the recovery

Method of measurement

Cuff pressure monitoring device

Intervention groups

1

Description

After general anesthesia, warm saline was applied for the patients in group 1 (n=40), 0.15 mg/kg Dexamethasone was applied for the patients in group 2 (n=40), and saline (22 to 24 C) was applied for the patients in group 3 (n=40). The tympanic temperature was evaluated pre-operatively and intra-operatively and post-operatively. Shivering was evaluated and recorded post-operatively.

Category

Treatment - Drugs

2

Description

The placebo control group received distilled water and serum samples at room temperature (22-20 ° C) via infusion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar hospital

Full name of responsible person

Abolfazl Abdollahpoor

Street address

St. Amin

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Semnan University of Medical Sciences

Street address

Vice chancellor for research, Semnan University of Medical Sciences

City

Semnan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Semnan University of Medical Sciences

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

Semnan University of Medical Sciences

Full name of responsible person

Abolfazl Abdaollahpoor

Position

Anesthesiologist

Other areas of specialty/work

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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