

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Dexmedetomidine on postoperative shivering after general anesthesia for appendectomy

Protocol summary

2019-01-14, 1397/10/24

Study aim

Determine the effect of Dexmedetomidine on postoperative shivering after general anesthesia for appendectomy

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

The operation room of Kowsar hospital was similar in all of our patients. The environment and checked for similar light, environmental temperature, drugs and liquids were kept in same rooms with same temperature.

Participants/Inclusion and exclusion criteria

emergent appendectomy patient between 15-25 years old. patients with peritonitis, ASA* more 2, past medical history of malignant hyperthermia, seizure, anaphylaxis, cardiovascular disease, dyspnea, diabetes mellitus, renal disease, liver disease, substance use, alcohol use, antiepileptic agent use, psychologic disorders, NSAIDs and usage of any other opioids or drugs for decreasing pain were excluded

Intervention groups

45 Patients was administered dexmedetomidin

Main outcome variables

Shivering Pain scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120801010471N4**

Registration date: **2019-01-14, 1397/10/24**

Registration timing: **retrospective**

Last update: **2019-01-14, 1397/10/24**

Update count: **0**

Registration date

Registrant information

Name

Milad Masaeli

Name of organization / entity

Kurdistan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3356 5240

Email address

drmilmas@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2018-05-03, 1397/02/13

Trial completion date

2018-06-22, 1397/04/01

Scientific title

Effect of Dexmedetomidine on postoperative shivering after general anesthesia for appendectomy

Public title

Effect of Dexmedetomidine on postoperative shivering after general anesthesia for appendectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Emergent appendectomy patients

Exclusion criteria:

Patients with peritonitis Past medical history of malignant hyperthermia Seizure Anaphylaxis Cardiovascular disease Diabetes mellitus Renal disease Substance use Liver disease Alcohol use Anti epileptic agent use Psychological disorders NSAIDs and usage of any other opioids or drugs for decreasing pain ASA more 2

Age

From **15 years** old to **25 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

The personnel that fulfill the questionnaire , nurse,anesthesiologist, data analysand did not know the patients.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kurdistan University of Medical Sciences

Street address

Pardis of Kurdistan University of Medical science, Pasdaran Ave, Azadi Square

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.MUK.REC.1395.385

Health conditions studied

1

Description of health condition studied

Shivering after appendectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Shivering scale

Timepoint

Immediately after general anesthesia, 5, 15, 30, and 60 minutes after general anesthesia

Method of measurement

Shivering was evaluated using a 5-point scale. The scale used was;0 = no shivering; 1 = observation of one or more of the following: piloerection, peripheral vasoconstriction, peripheral cyanosis without other causes, and/or no visible muscular activity; 2 = visible muscular activity confined to 1 muscle group; 3 = visible muscular activity in more than 1 muscle group; 4 = gross muscular activity involving the entire body.

Secondary outcomes

1

Description

Pain Scale

Timepoint

5,10,15,20

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: Fentanyl 2 μ /kg as a premedication, Thiopental sodium:5mg/kg and succinylcholin: 1.5mg/kg as induction of anesthesia were administered. Maintenance of anesthesia consists of Isoflurane 1.3 VOL% plus N2O and oxygen in the same concentration (3 L/min). The operation room was similar in all of our patients. The environment and checked for similar light, environmental temperature, drugs and liquids were kept in same rooms with same temperature.Intra venous fluid was infused 7cc/kg Ringer 5-7 minutes before induction of anesthesia. Pre oxygenation by 5-6 liter oxygen by anesthetic mask were done in all patients. Intra venous maintenance was 4cc/kg/h plus 3cc/kg instead of every milliliter of bleeding. Bleeding calculated by gathering the gases in the operation field and the blood in the

suction bottle. Temperature was measured base on tympanic membrane temperature in at minutes baseline time,5,15,30,60 after induction of anesthesia.We monitored non invasive blood pressure, puls oximetry, EKG monitoring (lead 2). We administered 1μ/kg dexmedetomidin intravenously 20 minutes before induction of anesthesia during 10 minutes and slowly (1μ/kg diluted in 10cc stree water)in intervention group.

Category

Treatment - Drugs

2

Description

Control group: Fentanyl 2μ/kg as a premedication, thiopental.sodium:5mg/kg and succinylcholin: 1.5mg/kg as induction of anesthesia were administered. Maintenance of anesthesia consists of Isoflurane 1.3 VOL% plus N2O and oxygen in the same concentration (3 L/min).The operation room was similar in all of our patients. The environment, and checked for similar light, environmental temperature, drugs and liquids were kept in same rooms with same temperature.Intra venous fluid was infused 7cc/kg Ringer 5-7 minutes before induction of anesthesia.pre oxygenation by 5-6 liter oxygen by anesthetic mask were done in all patients. Intra venous maintenance was 4cc/kg/h plus 3cc/kg instead of every milliliter of bleeding. Bleeding calculated by gathering the gases in the operation field and the blood in the suction bottle.Temperature was measured base on tympanic membrane temperature in at minutes baseline time,5,15,30,60 after induction of anesthesia.We monitored non invasive blood pressure, puls oximetry, EKG monitoring (lead 2).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar hospital

Full name of responsible person

Milad Masaeli

Street address

Kowsar hospital, Pasdaran Ave, Azadi Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Dr.Ebrahim Ghaderi

Street address

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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

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Milad Masaeli

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the information in the article will be presented

When the data will become available and for how long

2020

To whom data/document is available

All people related to health

Under which criteria data/document could be used

All people related to health

From where data/document is obtainable

Milad Masaeli

What processes are involved for a request to access data/document

Email to Milad Masaeli and get it

Comments