

# 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 $\mu$ /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

##### City

Sanandaj

##### Province

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##### Postal code

66177-13446

##### Phone

+98 87 3361 1310

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+98 87 3361 1310

##### Email

drmilmas@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sanandaj University of Medical Sciences

##### Full name of responsible person

Dr.Ebrahim Ghaderi

##### Street address

Pardis of Kurdistan University of Medical science,  
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##### Phone

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+98 87 3366 4654

##### Email

heydari132@muk.ac.ir

#### 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

##### Street address

Kowsar hospital, Pasdaran Ave, Azadi Square

##### City

Sanandaj

##### Province

Kurdistan

**Postal code**  
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drmilmas@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Sanandaj University of Medical Sciences  
**Full name of responsible person**  
Milad Masaeli  
**Position**  
Resident of Anesthesia  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Sanandaj University of Medical Sciences  
**Full name of responsible person**  
Milad Masaeli  
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Resident of Anesthesia  
**Latest degree**  
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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