

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparing the efficacy of intravenous bolus Dexmedetomidine and mepridine on the treatment of shivering following general anesthesia

Protocol summary

stop shivering and stabilize hemodynamic effects

Study aim

Comparison of the effect of intravenous bolus Dexmedetomidine and Mepridine on the treatment of shivering following general anesthesia

Design

A total of 100 patients will be selected according to studies and statistical calculations with inclusion criteria after surgery and discharged from anesthesia divided into two groups of intervention and control. The intervention group will receive Dexmedetomidine and the control group will receive Pethidine. The study is a randomized, double-blind, placebo-controlled clinical trial.

Settings and conduct

The study will be conducted in the recovery ward of Tabriz Imam Reza Hospital. The control group will receive Pethidine (Auxir-Iran Co.) 10 mg and the intervention group will use Dexmedetomidine (Imagen-Iran) 1 mg / kg body weight and then hemodynamic variables of patients including blood pressure and the patient's heart rate, blood oxygen saturation and axillary temperature will be recorded every 5 minutes by the anesthesiologist. Also, the severity of shivering in patients, the rate of response to treatment within 15 minutes of treatment initiation, and the duration of shivering will be documented in both groups. In this study, patients and anesthesiologists are blinded to the study.

Participants/Inclusion and exclusion criteria

Inclusion: Patients with ASA grade one or two in the age group of 18 to 65 years who have had grade 3 or 4 postoperative shivering; Exclusion: Patients under 18 or over 65 years of age, Previous sensitivity to Pethidine and Dexmedetomidine and patient's low blood pressure

Intervention groups

Dexmedetomidine will be used in the intervention group and Pethidine will be used in the control group.

Main outcome variables

Primary outcome: Time required for shivering and
Secondary outcome: Minimum dose of drug needed to

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150125020795N4**

Registration date: **2019-10-04, 1398/07/12**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-04, 1398/07/12**

Update count: **0**

Registration date

2019-10-04, 1398/07/12

Registrant information

Name

Samad Golzari

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3556 6183

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-19, 1398/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of intravenous bolus Dexmedetomidine and mepridine on the treatment of shivering following general anesthesia

Public title

The efficacy of intravenous bolus Dexmedetomidine and mepridine on the treatment of shivering following general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with ASA grade one or two Age range of 18 to 65 years After surgery, the patient has grade 3 or 4 shivering anesthesia.

Exclusion criteria:

Patients under 18 or over 65 years Previous sensitivity to pethidine or dexmedetomidine Patient's low blood pressure

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients wishing to participate in the study who meet the inclusion criteria will be selected as available sampling and then randomly assigned to two control and intervention groups using Randlist software.

Blinding (investigator's opinion)

Double blinded

Blinding description

An anesthesiologist who evaluates patients' response to the prescribed drug and also patients who are unaware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht St., Tabriz

City

Tabriz

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East Azarbaijan

Postal code

5166614766

Approval date

2019-07-03, 1398/04/12

Ethics committee reference number

IR.TBZMED.REC.1398.400

Health conditions studied**1****Description of health condition studied**

Shivering following general anesthesia

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes**1****Description**

Stop shivering

Timepoint

After surgery and the patient is discharged from anesthesia, shivering will be recorded within 15 minutes of treatment initiation and shivering time.

Method of measurement

Observe and record the severity (shivering grade) and duration of shivering

Secondary outcomes**1****Description**

Hemodynamic effects

Timepoint

After surgery and the patient is discharged from anesthesia, Patients with Grade 3 and 4 shivering, blood pressure and heart rate, oxygen saturation and axillary temperature will be measured every 5 minutes.

Method of measurement

Blood pressure and heart rate measurement using a monitoring and oxygen saturation percentage using an pulseoximeter and axillary temperature using a digital thermometer

Intervention groups

1

Description

Intervention group: In the intervention group, dexmedomidine (Imagen-Iran) will be used 1 µg / kg body weight.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive 10 mg of pethidine (Exir - Iran).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Samad Eslam Jamal Golzari

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Department of Anesthesiology., Faculty of Medical Sciences., Golgasht Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Samad Eslam Jamal Golzari

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available