

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of the effectiveness and speed of shivering treatment after general anesthesia with pethidine and doxapram in patients undergoing orthopedic surgery and urological surgery referred to Firoozgar Hospital in Tehran.

Protocol summary

Study aim

Determining the effectiveness and speed of shivering treatment after general anesthesia with pethidine and doxapram.

Design

This study is a double-blind, randomized, phase 3 clinical trial with control group, with parallel groups and 56 patients and uses block randomization method.

Settings and conduct

Patients seeking orthopedic or urological surgery undergo standard anesthesia. When patients regain consciousness and have chills, all non-pharmacological procedures such as warming or covering the patient with a blanket are performed. If there is no response to treatment, patients are divided into two groups. In the first group, selected patients are injected with pethidine based on their weight, and in the second group, patients are injected with doxapram based on their weight, and the findings are recorded and analyzed based on the objectives. This study is performed in Firoozgar Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ASA I, II anesthesia level, Patients aged 20 to 60 years undergoing orthopedic surgery and nephrology, Surgery less than 4 hours
Exclusion criteria: History of lung disease, Drug allergy to pethidine or doxapram.

Intervention groups

Group 1: Patients who have not responded to non-pharmacological treatment of shivering after surgery and will be injected with pethidine based on their weight.
Group 2: Patients who have not responded to non-pharmacological treatment of shivering after surgery and will be injected with doxapram based on their weight.

Main outcome variables

Shivering after surgery, Hypoxia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140109016151N9**

Registration date: **2021-03-12, 1399/12/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-12, 1399/12/22**

Update count: **0**

Registration date

2021-03-12, 1399/12/22

Registrant information

Name

Alireza Pournajafian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8894 6762

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness and speed of shivering treatment after general anesthesia with pethidine and doxapram in patients undergoing orthopedic surgery and urological surgery referred to Firoozgar Hospital in Tehran.

Public title

Comparison of effectiveness and speed of shivering treatment after general anesthesia with pethidine and doxapram.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with ASA I, II anesthesia level Patients aged 20 to 60 years undergoing orthopedic and urological surgery Surgery less than 4 hours

Exclusion criteria:

History of lung disease Drug allergy to pethidine or doxapram

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block, we divide 4 people into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Fifth floor, Central staff, Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

8874113911

Approval date

2020-08-09, 1399/05/19

Ethics committee reference number

IR.IUMS.FMD.REC.1399.321

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

orthopedic surgery

ICD-10 code

M96.62

ICD-10 code description

Fracture of humerus following insertion of orthopedic implant, joint prosthesis, or bone plate

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

Shivering after surgery

Timepoint

After surgery

Method of measurement

observation

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

Hypoxia

Timepoint

After surgery
Method of measurement
Pulse oximeter

Intervention groups

1

Description

Intervention group: Patients who have not responded to non-pharmacological treatment of chills after surgery and are injected with pethidine made by Caspian Pharmaceutical Company (50 mg ampoule per cc) .To treat chills, 25 mg of pethidine is injected in a single dose.

Category

Treatment - Drugs

2

Description

Intervention group: Patients who did not respond to non-pharmacological treatment of shivering after surgery were injected with doxapram, a Caspian drug company based on weight. According to the treatment protocol, the dose of doxapram is 0.7mg / kg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Alireza Pournajafian

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Anesthesia Department, Firouzgar Hospital ,Beh-afarin street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Alireza Pournajafian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

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

Iran University of Medical Sciences

Full name of responsible person

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Other areas of specialty/work

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