Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparison effects of three methods:Pethidine, warm intravenous fluids and combination warming (warm intravenous fluids with humid warm oxygen) on severity of postoperative shivering

Protocol summary

Summary

The purpose of this study is to compare three methods of using Pethidine, warm intravenous fluids and combined warming(Intravenous fluids with humid warm oxygen) on the severity of postoperative shivering in general anesthesia. Patients was scheduling in class 1 and 2 Society of Anesthesiology America (ASA) under GA abdominal surgery and entering the recovery room and have shivering with 1, 2, 3 degree will be selected. This study is a randomized controlled trial that will be implemented on 96 abdominal surgery patient with general anesthesia .it will be double blind.at first will be appointed the degree of shivering patient in recovery room and patient will be set in randomize three groups . Intravenous Pethidine 0.4mg/kg accompany with room temperature ringer serum and humid- room temperature oxygen will be used for Group 1 ,for group two will be used 38 ° C ringer serum amount 3cc/kg every 10minutes to 20 minutes accompany with humid- room temperature oxygen and placebo(3cc normal salin0.9%) and for group three will be used combination warming(38 ° C ringer serum and humid warm oxygen amount 8lit/min with mask accompany with placebo) .the degree of shivering and tympani c temperature and time of stop shivering will be recorded after use every methods at 10 and 20 minutes .and will be compared groups in end.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012016278N1**
Registration date: **2014-06-25, 1393/04/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-25, 1393/04/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2014-05-05, 1393/02/15

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison effects of three methods:Pethidine, warm intravenous fluids and combination warming (warm intravenous fluids with humid warm oxygen) on severity of postoperative shivering

Public title

The comparison effects of pethidine, warm intravenous fluids and combination warming (warm intravenous fluids

with humid warm oxygen) on severity of postoperative shivering by general anesthesia patients in recovery room

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:operation under general anesthesia؛ individuals 20-60years؛ the category of America Society of Anesthesiology (ASA) are class 1 and 2, ASA1 (people with normal health without systemic diseases such as heart disease and respiratory and endocrine and...) ASA2 (people that have a mild controlled systemic disease and not limit the patient) ;degree1,2,3 of shivering; normothermic patients :the oral temperature will be between 36/5 to 37/5° C ;the lack of reception (corticosteroids, non steroidal analgesics , anti hypertensive drugs , anti seizure drugs); lack of received blood and blood products;patient without BP and SPO2 changes;consent to participate up to the end study. Exclusion criteria :spinal anesthesia;individuals below20 and up 60 years ; ASA 3,4 such as(endocrine disorders , cardiovascular diseases , hypertension, ischemic heart disease , obstructive lung disease and cerebral palsy patient and...) ;fever;addiction;hyperthermia and hypothermia; reception(corticosteroids, non steroidal analgesics , anti hypertensive drugs , anti seizure drugs); received blood and blood products ; degree 4 of shivering ;patients who will not consent to participate up to the end study ; patients with BP changes are more 5mm/ hg ;decrease in spo2 than 15%.

Age

From **19 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **96**

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

Birjand University of Medical Sciences

Street address

Central Organization of Birjand University of Medical Sciences and Health Services, Ghaffari Street, Birjand, South Khorasan

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Postal code

۴۴۳۰۰۷۶

Approval date

2014-05-04, 1393/02/14

Ethics committee reference number

1393-02-03

Health conditions studied

1

Description of health condition studied

Shivering

ICD-10 code

T80-T88

ICD-10 code description

Complications of surgical and medical care, not elsewhere classified

Primary outcomes

1

Description

Shivering

Timepoint

Postoperative

Method of measurement

Patient Observation

Secondary outcomes

1

Description

Temperature

Timepoint

Postoperative

Method of measurement

Tympanic thermometer

Intervention groups

1

Description

combination warming(intravenous warming serum and humid warm oxygen 8lit/min)

Category

Treatment - Drugs

2

Description

warm intravenous fluids(38 ° C ringer serum)
Category
Treatment - Drugs

3

Description
intravenous pethidin 0.4mg/kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr.Ahmad Ali Nasiri Forg
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Sponsors / Funding sources

1

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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
Birjand University of Medical Science
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

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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