

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing the effect of moderate hypothermia and normothermia on the dosage of anesthetic medication and recall of anesthesia in drug-addicted patients undergoing coronary artery bypass surgery.

Protocol summary

Summary

Objective: Comparing the effect of moderate hypothermia and normothermia on the dosage of anesthetic medication and recall in drug-addicted patients undergoing coronary artery bypass surgery. Design: Randomized, Double blind, Target sample size: 80 People The major inclusion criteria: Patients between 30 and 70 years old with opium addiction who are candidate for elective coronary bypass on-pump surgery. The major exclusion criteria: History of previous anesthesia for cardiac surgery; American Society of Anaesthesiologists physical status classification more than 4, History of alcohol consumption; History of addiction to opium; History of long-term use of psychotropic drugs or tranquilizers. Intervention group: Hypothermia conditions, after aortic cannulation by cardiopulmonary bypass pump, body is slowly cooled till (28-32 ° C) Control group: Normothermia conditions, at the end of surgery patient's body temperature is warmed till (36 Centigrade) by blanket under patient. Primary outcome measure: The total amount of medication (Fentanyl and Propofol) and additional medication to achieve the desired depth of anesthesia (40-60), During surgery and at the time of extubation, clinical check list by researchers; Awareness during anesthesia, 24 hour after extubation by questionnaire with open questions

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050513159N5**

Registration date: **2014-06-23, 1393/04/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-23, 1393/04/02

Registrant information

Name

Shima Sheybani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3764 7230

Email address

sheybanish@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2014-05-03, 1393/02/13

Expected recruitment end date

2015-05-03, 1394/02/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of moderate hypothermia and normothermia on the dosage of anesthetic medication and recall of anesthesia in drug-addicted patients undergoing coronary artery bypass surgery.

Public title

The effect of moderate hypothermia on the dosage of anesthetic medication and recall of anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

The major inclusion criteria: Patients between 30 and 70 years old with opium addiction who are candidate for elective coronary bypass on-pump surgery. The major exclusion criteria: History of previous anesthesia for cardiac surgery; ASA Physical Status Classification System more than 4, History of alcohol consumption; History of addiction to opium; History of long-term use of psychotropic drugs or tranquilizers.

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

patients are divided randomly by encoding. Researchers and patients are unaware

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad

City

Mashhad

Postal code

Approval date

2013-09-09, 1392/06/18

Ethics committee reference number

920405

Health conditions studied

1

Description of health condition studied

investigation of effect of anesthesia drug consumption

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

Primary outcomes

1

Description

The total amount of medication (Fentanyl and Propofol) to achieve the desired depth of anesthesia

Timepoint

During surgery and at the time of extubation after surgery

Method of measurement

Clinical check list by researchers and the bispectral Index monitor

2

Description

Awareness during anesthesia

Timepoint

24 hour after extubation

Method of measurement

Questionnaire with open questions

3

Description

Depth of anesthesia (40-60)

Timepoint

During surgery and at the time of extubation after surgery

Method of measurement

The bispectral Index monitor

4

Description

The total amount of extra medication (Fentanyl and Propofol) to achieve the desired depth of anesthesia

Timepoint

During surgery and at the time of extubation after surgery

Method of measurement

Clinical check list by researchers

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hypothermic condition, after aortic

cannulation by cardiopulmonary bypass pump, body is slowly cooled till (28-32 ° C)

Category

Diagnosis

2

Description

Control group: normothermic condition, At the end of surgery patient's body temperature is warmed till (36 Centigrade) by blanket under patient

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Shima Sheybani

Street address

Anesthesia group, Ghaem Hospital, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street, Mashhad

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Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

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

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Shima Sheybani

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Imam Reza Hospital

Full name of responsible person

Ali Rahdari

Position

Resident

Other areas of specialty/work

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Web page address**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