Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing sleep quality of patients after coronary artery bypass grafting by pulsatile flow and non-pulsatile flow in cardiopulmonary bypass

Protocol summary

Study aim
Comparison sleep quality of patients after coronary artery bypass grafting by pulsatile flow and non-pulsatile flow in cardiopulmonary bypass

Design
Double blinded clinical trial with control group that has two parallel groups with sample size of 47 persons.

Settings and conduct
Patients that referred to Isfahan Chamran Hospital who were included in the study were randomly divided into two groups. Patients in the intervention group during aortic cross clamp gave pulsatile blood flow. Pittsburgh sleep quality questionnaire was completed before and one month after surgery by rater.This study was double_blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients under CABG surgery, Patient consent, The BMI of less than 35, The age of less than 70 years and ability to respond correctly to the questionnaire. Exclusion criteria: History of any stroke, Poor sleep quality before surgery, Chronic consumption of alcohol and antidepressants.

Intervention groups
26 patients were under pulsatile flow during aortic clamp.

Main outcome variables
Sleep quality score based on PSQI questionnaire

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190807044469N1**
Registration date: **2020-01-12, 1398/10/22**
Registration timing: **retrospective**

Last update: **2020-01-12, 1398/10/22**
Update count: **0**

Registration date
2020-01-12, 1398/10/22

Registrant information

Name
Nahid Jahannama

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-31, 1398/05/09

Expected recruitment end date
2019-11-19, 1398/08/28

Actual recruitment start date
2019-07-31, 1398/05/09

Actual recruitment end date
2019-11-20, 1398/08/29

Trial completion date
2019-12-20, 1398/09/29

Scientific title
Comparing sleep quality of patients after coronary artery bypass grafting by pulsatile flow and non-pulsatile flow in cardiopulmonary bypass

Public title
The effect of pulsatile flow on sleep quality

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients under CABG surgery Patient consent The age of

less than 70 years The BMI of less than 35 Ability to respond correctly to the questionnaire

Exclusion criteria:

History of any stroke Poor sleep quality before surgery Chronic consumption of alcohol and antidepressants

Age

To **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **47**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling method is a simple Non-probability and randomization using SPSS software

Blinding (investigator's opinion)

Double blinded

Blinding description

Each participant is numbered randomly using SPSS software. The patient and the rater are unaware of the type of procedure.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jerib

City

Isfahan

Province

Isfehan

Postal code

73461-81746

Approval date

2019-07-31, 1398/05/09

Ethics committee reference number

IR.MUI.MED.REC.1398.235

Health conditions studied

1

Description of health condition studied

Sleep Quality

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep quality

Timepoint

Before and one month after surgery

Method of measurement

Pittsburgh Sleep Quality Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pittsburgh questionnaire was completed two days before and a month after surgery. The same methods for anesthesia and surgery, heart-lung machine, oxygenator, arterial filter and cannula was used for all patients. During surgery, body temperature of patients was reduced to 34 celsius degrees and the mean arterial pressure was kept between 80-90 mmHg. After the clamping aorta and injection of cardioplegia and heart arrest, patients of intervention group were under pulsatile blood flow during clamping aortic.

Category

Treatment - Surgery

2

Description

Control group: All condition are the same as the intervention group except that patients were under non pulsatile blood flow in all the time CPB

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran Hospital

Full name of responsible person

Nahid Jahannama

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Vice-Chancellor for Research and Technology - Isfahan University of Medical Sciences
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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
Esfahan 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
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Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Because of secondary data analyze
Study Protocol
No - There is not 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