

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Anesthesia's Effect with Gabapentin and Parastamol as a precursor on hemodynamic values during anesthesia with Remy Fentanyl in adult heart surgery

Protocol summary

Study aim

Investigating and comparing the effect of gabapentin and paracetamol on hemodynamic values during heart surgery in adults

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 30 patients in each group, which rand function of Excel software was used for randomization.

Settings and conduct

This study was conducted in Chamran Hospital, Isfahan, on patients undergoing heart surgery, and the study was conducted in a double-blind manner.

Participants/Inclusion and exclusion criteria

Patients who undergo heart surgery

Intervention groups

paracetamol group, who are given one gram of intravenous paracetamol one hour before the operation
Gabapentin group, which is given 100 mg of paracetamol one hour before the operation

Main outcome variables

Hemodynamic stability including heart rate and blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221210056764N1**

Registration date: **2023-06-13, 1402/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2023-06-13, 1402/03/23**

Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Amene Roodhelle

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 5555

Email address

dr.amene1990@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Anesthesia's Effect with Gabapentin and Parastamol as a precursor on hemodynamic values during anesthesia with Remy Fentanyl in adult heart surgery

Public title

The effect of preemptive in cardiac surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Adults undergoing heart surgery No emergency heart surgery

Exclusion criteria:
Uncontrolled underlying disease

Age
From **20 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple randomization technique was employed in this study with the statistical analysis being conducted using SPSS version 20 software . Upon assigning a unique code to each patient , the randomization software was utilized to allocate patients into either the control or test groups . Patients assigned to the test group were administered premedication prior to the operation and Remifentanyl during the procedure to manage any pain . The control group , on the other hand , received placebo before the operation and Morphine and Fentanyl during the operation to alleviate pain .

Blinding (investigator's opinion)

Triple blinded

Blinding description

After informing the patient that it is necessary to receive pre-medication before surgery to have fewer complications, one of the drugs studied will be given to him

Placebo

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

Shohadaie Soffe Ave., Alzahra hospital

City

Isfahan

Province

Isfahan

Postal code

8174675731

Approval date

2022-11-27, 1401/09/06

Ethics committee reference number

IR.MUI.MED.REC.1401.313

Health conditions studied

1

Description of health condition studied

Ischemic cardiac disease

ICD-10 code

T82.8

ICD-10 code description

Other specified complications of cardiac and vascular prosthetic devices, implants and grafts

Primary outcomes

1

Description

In-operative hemodynamic values

Timepoint

Measurement of hemodynamic levels before anesthesia and every 15 minutes until the end of anesthesia

Method of measurement

Mercury pressure gauge

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will be given 100mg Gabapentine (capp Gabapentine 100mg - Sanamed)the night before surgery and 1 gram of intravenous Paracetamol one hour before the start of surgery and during operation , patients receive Remofentanyl if necessary.

Category

Placebo

2

Description

Control group: In this group patients receive placebo and during operation patients receive Morphine and Fentanyl if necessary .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Dr. Mojtaba Mansuri

Street address

Dr. Chamran Shahid Heart Hospital . salman Ave

City

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Province

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8158388994

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

dr Mojghan Mortazavi

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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

Esfahan University of Medical Sciences

Full name of responsible person

Amene Roodhelle

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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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