

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of interavenous Ketamine during cardiopulmonary bypass on post operative patients agitation

Protocol summary

Summary

The study of double-blind clinical trial, is done with estimating the effect of ketamine injection on the agitation after an open heart surgery. 40 male patients over 55, referred to Golestan and Imam Khomeini's hospital in Ahwaz, are divided into 2 groups of 20 patients and receive pre-medication with morphine 0.1mg/kg and intramuscular promethazine of 0.5 mg/kg. induction is done with diazepam 0.15 mg/kg, fentanyl 3-10 µg/kg, STP 2mg/kg, atracurium 0.5 mg/kg or atracurium 0.15 mg/kg. Anesthesia goes on with Atracurium or Cisatracurium 0.3 mg/kg and propofol 50µg/kg/min and isofluran of %0.4-%1.6. ketamine at a dose of 0.5 mg/kg is prescribed for the patients before sternotomy and before the pumping. In the second group, placebo is used (saline 0.9%) with the same size. Agitation, during first 8 hours after the surgery is measured every 2 hours and then every 8 hours for two days with Riker Sedation-Agitation Scale (SAS). Conditions during the study: ACT more than 480; MAP :60-80 ; Heparin 300 U/kg ; heat on pump 32 °C ; cardioplegic solution Hyperkalemic 15 cc/kg intervals of 20min ; CBP flow 2.4-2.5 L/min/m² ; PRIME solution of normal saline serum ; Reverse Heparin with protamine sulfate ; ABG (Pco₂= 35-40) Inclusion criteria: Males over 55 years Exclusion criteria CVA in past three years ; Permanent Pace maker ; Hepatic dysfunction with ALT, AST more than 2 fold normal ; CRF (Cr more than 2) ; Delirium week before surgery ; Documented cognitive disorders ; Psychosis ; Drug Abuse

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090610762N1**

Registration date: **2013-03-24, 1392/01/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-24, 1392/01/04

Registrant information

Name

Anahita Babaei

Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Jundishapur University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of interavenous Ketamine during cardiopulmonary bypass on post operative patients agitation

Public title

The effect of Ketamine on post open heart surgery patients agitation

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Males over 55 years Exclusion criteria:
 CVA in past three years; Permanent Pace maker ;
 Hepatic dysfunction with ALT, AST more than 2 fold
 normal ; CRF(Cr morethane2) ' Delirium week before
 surgery ; Documented cognitive disorders ; Psychosis ;
 Drug Abuse

Age
 From **55 years** old to **80 years** old

Gender
 Male

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **40**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jundishapur University of Medical Sciences,Vice
 Chancellor for Research and Technology

Street address

Vice Chancellor for Research and
 Technology,Jundishapur University of Medical
 Sciences,Esfand st, Golestan Blvd

City

Ahwaz

Postal code

Approval date

2012-06-09, 1391/03/20

Ethics committee reference number

ETH-487

Health conditions studied

1

Description of health condition studied

agitation

ICD-10 code

F43.0

ICD-10 code description

Acut stress reaction

Primary outcomes

1

Description

Post operative agitation

Timepoint

3 days after surgery (8 hours every 2 hours, then every 8
 hours)

Method of measurement

SAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Group 1 received intravenous ketamine 0.5 mg per
 kilogram of body weight before sternotomy and before
 the pump

Category

Treatment - Drugs

2

Description

In group 2, intravenous saline 0.5 mg per kilogram of
 body weight before sternotomy and before the pump

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz Jundishapur University Medical Sciences

Full name of responsible person

Anahita babaei

Street address

Golestan hospital, golestan Blvd / Imam Khomeiny
 hospital, Azadegan street

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Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jundishapur University of Medical Sciences,Vice
 Chancellor for Research and Technology

Full name of responsible person
Dr Mostafa Fegghi

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City
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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
Jundishapur University of Medical Sciences,Vice
Chancellor for Research and Technology

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
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Full name of responsible person
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Other areas of specialty/work

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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