

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

comparison the sedative effect of propofol and ketofol on patients undergoing coronary artery bypass graft (CABG) in intensive care unit (ICU)

Protocol summary

Summary

The aim of this single blind clinical trial study was to compare the sedative effects of propofol and ketofol in patients undergoing CABG in ICU in Afshar Hospital. After ethics committee approval and obtaining informed consent, 45 patients 40-60 years old , ASA 1,2 divided in two groups. 30 minutes before entering the operating room, all patients received 0.1 mg / kg morphine plus 0.5 mg / kg promethazine IM. patients inducted with fentanyl 3_5 micro / kg , propofol 1mg / kg and Atracurium 0.5 mg / kg and then 3_4mg / kg / hr propofol and Atracurium 0.5mg / kg / hr for maintenance. At the end of the surgery patients transferred to the ICU . patient sedation was performed with propofol 15 micro / min / kg and propofol 15 micro / min / kg plus ketamine 3 micro/ min / kg in ketamine group . patient sedation was evaluated by a special algorithm (Richmond algorithm) with approved reliability and validity . pain score measured using Behavioral Pain Scale every two hours. After the patient extubation, delirium evaluated by ICU CAM criteria . In ICU, SBP, DBP, MAP and HR in both groups were measured and recorded, each 30 minutes at the first four hours, then each one hour after that until to extubation time.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510314583N7**
Registration date: **2016-08-20, 1395/05/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-20, 1395/05/30

Registrant information

Name

Hossein Moshtaghion

Name of organization / entity

Yazd University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

vice chancellor of research of Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2016-02-19, 1394/11/30

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison the sedative effect of propofol and ketofol on patients undergoing coronary artery bypass graft (CABG) in intensive care unit (ICU)

Public title

sedative effect of propofol and ketofol on patients undergoing coronary artery bypass graft (CABG)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients 40-60 years old with ASA 1,2 undergoing CABG in ICU in Afshar Hospital
Exclusion criteria: patients requiring inotropic drugs; patients with impaired renal tests; addicted patients ; ejection fraction <40%; patients requiring hospitalization in the ICU for more than 24 hours; patients with known psychiatric problems; patients with history of seizure

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

randomization was according to table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi university of medical sciences

Street address

Bahonar square , Yazd

City

Yazd

Postal code

Approval date

2016-01-06, 1394/10/16

Ethics committee reference number

IR.SSU.MEDICINE.REC.1394.332

Health conditions studied

1

Description of health condition studied

Ischaemic heart diseases

ICD-10 code

E120,E121,

ICD-10 code description

Ischaemic heart diseases

Primary outcomes

1

Description

pain

Timepoint

each two hours after the beginning of the process

Method of measurement

according to Behavioral Pain Scale (Questionnaire)

2

Description

heart rate

Timepoint

every 30 minutes at the first four hours and then each one hour after that until extubation

Method of measurement

by monitoring

3

Description

systolic blood pressure

Timepoint

every 30 minutes at the first four hours and then each one hour after that until extubation

Method of measurement

by monitoring

4

Description

diastolic blood pressure

Timepoint

every 30 minutes at the first four hours and then each one hour after that until extubation

Method of measurement

by monitoring

5

Description

mean arterial blood pressure

Timepoint

every 30 minutes at the first four hours and then each one hour after that until extubation

Method of measurement

by monitoring

6

Description

patient sedation

Timepoint

once

Method of measurement

by Richmond scale (Questionnaire)

Secondary outcomes

empty

Intervention groups

1

Description

intervention group 1: propofol 15 micro/kg/min once

Category

Treatment - Drugs

2

Description

intervention group 2 : propofol 15 micro/kg/min plus ketamin 3 micro/kg/min once

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital

Full name of responsible person

Dr Hossein Moshtaghion

Street address

Shahid Sadoughi hospital

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Shahid Sadoughi university of medical sciences.

Full name of responsible person

Dr Habib Nikokar

Street address

Shahid Sadoughi university of medical sciences, Yazd, Iran

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of Shahid Sadoughi 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

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Hossein Moshtaghion

Position

Assistant professor

Other areas of specialty/work

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Fax**Email**

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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