

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

comparative effect of propofol and ketamine sedation on cerebral oxymetry results in pediatric cardiac catheterisation

Protocol summary

Study aim

The effect of propofol and ketamine on the results of cerebral oximetry in children undergoing cardiac catheterization

Design

Clinical trial with two parallel groups, double-blind, randomized with flip the coin method, sample size of 44 patients

Settings and conduct

In Modares hospital cath. lab for all patients on awakening time, standard monitoring including pulse oximetry, electrocardiogram and NIBP as well as NIRS probe is connected and recorded. One group is given ketamine (1 mg per kg) for sedation with 0.1 mg per kg of midazolam and the other group is given propofol (1 mg per kg) with midazolam. Spo₂, NIBP, NIRS findings are monitored and recorded upon awakening, immediately after induction and every 5 minutes thereafter

Participants/Inclusion and exclusion criteria

Children referring to the cath lab. of Shahid Modares Hospital for diagnostic cardiac catheterization

Intervention groups

Ketamine intervention group and propofol intervention group

Main outcome variables

Cerebral oximetry number by near infrared spectroscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180724040575N1**

Registration date: **2020-09-19, 1399/06/29**

Registration timing: **prospective**

Last update: **2020-09-19, 1399/06/29**

Update count: **0**

Registration date

2020-09-19, 1399/06/29

Registrant information

Name

kamal fani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2207 4095

Email address

kamalfani@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative effect of propofol and ketamine sedation on cerebral oxymetry results in pediatric cardiac catheterisation

Public title

Comparison of the effect of propofol and ketamine on brain oximetry results

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children referring to the cath lab. of Shahid Modares Hospital for diagnostic cardiac catheterization
Exclusion criteria:
Parental dissatisfaction Known allergy to ketamine or propofol History of seizure or other neurological diseases

Age

From **6 months** old to **60 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization by flip the coin method. The allocation of two sides of a coin to each of the study groups was determined and then the number of coin samples was thrown and recorded

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and parents and the registrant of the research questionnaire (about used medication) are blind. All parents have approved the consent form but are not aware of the grouping The anesthesiologist will prescribe a sedative based on the pre-determined group, but the person recording the questionnaire in the cath. lab. control room is not aware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti University of Medical Sciences

Street address

Taleghani Hospital, velenjak, Tehran. Iran

City

Tehran

Province

Tehran

Postal code

19969111151

Approval date

2019-12-15, 1398/09/24

Ethics committee reference number

IR.SBMU.REC.1398.137

Health conditions studied

1

Description of health condition studied

Diagnostic cardiac catheterization in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Cerebral oximetry number by near infrared spectroscopy

Timepoint

Before and after catheterization every 5 minutes to the end of the procedure and transfer to the recovery room.

Method of measurement

Near infrared spectroscopy

Secondary outcomes

1

Description

heart beat

Timepoint

5 minutes

Method of measurement

By pulse oximetry and electrocardiogram monitoring device

2

Description

blood oxygen saturation

Timepoint

5 minutes

Method of measurement

By pulse oximetry device

3

Description

blood pressure

Timepoint

5 minutes

Method of measurement

by non-invasive sphygmomanometer

Intervention groups

1

Description

Intervention group: ketamine(As an anesthetic drug

commonly used in sedation of children undergoing the procedure) is administered intravenously at doses of 1 mg per kg with control of vital signs and hemodynamics. The drug is repeated throughout the procedure based on the patient's reactions and the decision of the responsible anesthesiologist. Number of injections, total dose and duration of procedure and patient recovery time are recorded. Ketamine drug produced by Rotex Medica with an initial concentration of 50 mg / ml, which is diluted to 2 mg / ml is used.

Category

Treatment - Drugs

2**Description**

Intervention group: propofol (As an anesthetic drug commonly used in sedation of children undergoing the procedure) is administered intravenously at doses of 1 mg per kg with control of vital signs and hemodynamics. The drug is repeated throughout the procedure based on the patient's reactions and the decision of the responsible anesthesiologist. Number of injections, total dose and duration of procedure and patient recovery time are recorded. Baxter 1% propofol is used, which is diluted up to 2 mg per milliliter.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Modarres Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Kamal Fani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Latest degree

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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

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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