Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of anesthesia method with combined ketamine / sevoflurane and combined propofol/ketamine and its efficacy on blood pressure and heart rate changes in patients with diagnostic angiography

Protocol summary

Summary

The purpose of this study is Comparison of anesthesia method with combined ketamine / sevoflurane and combined propofol/ketamine and its efficacy on blood pressure and heart rate changes in patients with diagnostic angiography. Patients aged 2 to 8 years, ASA I, II without metabolic, kidney and liver disease will be studied. 60patient refferd to Sina Hospital Tehran divided into 2 groups. in first group, induction of anesthesia will performed with ketamine and will maintained with sevoflurane and the Laryngeal mask airway. In the second group, induction and maintaine of anesthesia will performed with mixed propofol / ketamine and Laryngeal mask airway. in each group, heart rate, respiratory rate and artrial blood pressure will be checked and The 2 groups will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015013012642N12**
Registration date: **2015-02-27, 1393/12/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-02-27, 1393/12/08

Registrant information

Name
Majid Golestani Eraghi
Name of organization / entity
Shahid Beheshti University Of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Tehran University of Medical Sciences

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anesthesia method with combined ketamine / sevoflurane and combined propofol/ketamine and its efficacy on blood pressure and heart rate changes in patients with diagnostic angiography

Public title

The effect of anesthetic drugs on blood pressure and heart rate changes in patients with diagnostic angiography

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: ASA I,II, Children 2 to 8 years, Written consent from the parent exclusion criteria: patients with pulmonary, hepatic, renal and metabolic disease, Patients with a prior history of cardiac and thoracic surgery, Patients who need more airway support and

pulmonary care

Age
From **2 years** old to **8 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Tehran University of Medical Sciences

Street address
Ghods Ave, Keshavarz Boulevard

City
Tehran

Postal code

Approval date
2013-12-17, 1392/09/26

Ethics committee reference number
2172

Health conditions studied

1

Description of health condition studied
Effects of anesthetic drugs in diagnostic angiography

ICD-10 code
T88.7

ICD-10 code description
Unspecified adverse effect of drug or medicament

Primary outcomes

1

Description
Arterial oxygen pressure

Timepoint
Before and after induction of anesthesia

Method of measurement
artrial blood gaz analyzer device in mmHg

2

Description
Blood Pressure

Timepoint
Before and after induction of anesthesia

Method of measurement
Non-invasive barometer in mm Hg

Secondary outcomes

1

Description
Arterial pressure of carbon dioxide

Timepoint
Before and after induction of anesthesia.

Method of measurement
By the analyzer device in mmHg

2

Description
arterial pulmonary blood pressure

Timepoint
Before and after induction of anesthesia.

Method of measurement
by angiography in mmHg

Intervention groups

1

Description
in The first group, induction of anesthesia with intravenous injection ketamine with dose of one mg per killogeram and receive sevoflurane will started. After 3 minutes, Laryngeal mask airway will be inserted

Category
Prevention

2

Description
In the second group solution containing of 80 mg per liter ketamine / propofol and 0.1 mg per killogeram of the prepared solution was administered for induction of anesthesia then Anesthesia will performe with infusion of 0.01 mg per killogeram per minute of solution.Laryngeal mask will be inserted after 3 minutes

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Children Medical Center Hospital
Full name of responsible person
Majid Golestani Eraghi
Street address
Doctor Mohamed Gharib St, Keshavarz Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology of Tehran University of Medical Sciences
Full name of responsible person
Masood Yoonesian
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Central Organization of Tehran University of Medical Sciences, Ghods Ave, Keshavarz Boulvard
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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
Vice Chancellor for Research and Technology of Tehran 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Department of Anesthesiology, Tehran University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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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