Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effects of propofol, ketamine, and ketofol on controlling agitation in children after herniorrhaphy

Protocol summary

Study aim

Comparison of the effects of propofol, ketamine, and ketofol on controlling agitation in children after herniorrhaphy

Design

A double-blind randomized clinical trial with parallel groups and phase 3 will be conducted on 105 patients. Patients will be assigned to one of three groups receiving propofol, ketamine, or ketofol. Randomization will be performed with the block randomization method using Random allocation software.

Settings and conduct

In this double-blinded clinical trial study, children undergoing herniorrhaphy at Urmia Shahid Motahari Hospital in will be enrolled. In the operating room, patients will be placed under routine monitoring such as electrocardiography, pulse oximetry, and non-invasive blood pressure monitoring. After inducing general anesthesia with sevoflurane, 105 patients will be randomly assigned to one of three groups: propofol 0.5 mg, ketamine 0.5 mg, and ketofol 0.5 mg. The study will be conducted as a double-blind clinical trial. The patient and the primary researcher who will assess the outcomes will be blind of the patient's allocation into one of the intervention groups.

Participants/Inclusion and exclusion criteria

In this study, 105 children aged 2 to 4 years undergoing herniorrhaphy under general anesthesia will be included. Children with mental retardation, neurological and pulmonary diseases will not be included in the study.

Intervention groups

In all patients after induction of general anesthesia with sevoflurane, for patients in group one Propofol 0.5 mg/kg, in group two Ketamine 0.5 mg/kg, and in group three Ketofol 0.5 mg/kg will be injected intravenously.

Main outcome variables

Agitation score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201207049639N9**
Registration date: **2023-06-12, 1402/03/22**
Registration timing: **prospective**

Last update: **2023-06-12, 1402/03/22**
Update count: **0**

Registration date

2023-06-12, 1402/03/22

Registrant information

Name

Hadi Houshyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

hooshyar.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of propofol, ketamine, and ketofol on controlling agitation in children after herniorrhaphy

Public title
Investigating the effect of propofol, ketamine and ketofol on agitation after herniorrhaphy
Purpose
Other
Inclusion/Exclusion criteria
Inclusion criteria:
Children undergoing herniorrhaphy under general anesthesia Aged between 2-4 years Patients with physical status classified as ASA II and ASA III according to the criteria of the American Anesthesia Association (ASA).
Exclusion criteria:
Mental retardation Neurological diseases Anomaly of the upper airway History of asthma or other lung diseases Pulmonary infections in the last 4 weeks
Age
From **2 years** old to **4 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into interventions groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first the number of groups and the total number of the sample size will be entered, and then in the block section, the Block randomization method will be selected. Patients will be allocated in intervention groups based on generated numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be conducted as a double-blind clinical trial. The patient and the primary researcher who will assess the outcomes will be blind of the patient's allocation into one of the intervention groups. The syringes containing drugs will be similar in shape and size and the drug will be prescribed by an anesthesiologist (other than the outcome assessor). Therefore, the physician will be given a list of numbers generated by computer software, and the physician will assign patients to groups based on the order of the numbers, and finally, the groups will be labeled with letters A, B, and C.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2023-03-08, 1401/12/17
Ethics committee reference number
IR.UMSU.REC.1401.422

Health conditions studied

1

Description of health condition studied
Agitation after surgery
ICD-10 code
R45.1
ICD-10 code description
Restlessness and agitation

Primary outcomes

1

Description
Agitation score
Timepoint
After extubation, the time to leave the operating room, recovery and 30 minutes after surgery.
Method of measurement
Four-point scale for assessing of agitation

Secondary outcomes

1

Description
Pain severity
Timepoint
Recovery, 30 minutes after surgery
Method of measurement

Consolability cry activity leg face (FLACC)

2

Description
Heart rate
Timepoint
Every 15 minutes to one hour, and at hours 6, 12, and 24 after surgery.
Method of measurement
Pulse oximetry

3

Description
Vomiting
Timepoint
Within 24 hours after surgery
Method of measurement
Clinical examination

Intervention groups

1

Description
Intervention group: For patients in group one, after induction of general anesthesia with sevoflurane, propofol 0.5 mg/kg will be injected intravenously.
Category
Treatment - Other

2

Description
Intervention group: For patients in group two after induction of general anesthesia with sevoflurane, Ketamine 0.5 mg/kg will be injected intravenously.
Category
Treatment - Other

3

Description
Intervention group: For patients in group three after induction of general anesthesia with sevoflurane, Ketofol 0.5 mg/kg will be injected intravenously.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Shahid Motahhari hospital
Full name of responsible person
Dr. Hadi Hooshyar
Street address
Shahid Motahhari Hospital; Kashani street; Urmia; Iran.
City
Urmia
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5714783734
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Email
hooshyar.h@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
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gholizadeh.s@umsu.as.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Hadi Hooshyar
Position
Assistant professor
Latest degree

Specialist

Other areas of specialty/work
Anesthesiology

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Shahid Motahhari Hospital; Kashani street; Urmia; Iran.

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Information can be provided without patients' names

When the data will become available and for how long
After the article is published

To whom data/document is available
Researchers

Under which criteria data/document could be used
Only for research purposes

From where data/document is obtainable
Email to the corresponding author: hooshyar.h@umsu.ac.ir

What processes are involved for a request to access data/document
Email to the corresponding author: hooshyar.h@umsu.ac.ir

Comments