Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of intravenous ketamine and midazolam as a premedication in children undergoing cochlear implantation at the time of separation from parents

Protocol summary

Study aim

Inducing sedation for deaf and muteness children when leaving their parents for cochlear implantation.

Design

This prospective clinical study with parallel groups, double-blinded, will be performed on 74 children who will be referred to Baqiyatallah Hospital for cochlear implantation. Patients will be divided randomly into two groups of 37 patients, midazolam and ketamine.

Settings and conduct

This double-blind study will be conducted on children who will be referred to Baqiyatallah hospital for cochlear implantation. Patients will be randomly divided into midazolam and ketamine groups. The researcher's assistant who will be unaware of the type of used drugs will observe the child in the pre-operative room and fill out the SASS rating form for anxiety scoring. Then, another person will inject the medicine that will be encoded before (blindness will be kept). After calming the child, the researcher's assistant will fill out the form again by removing the child from the parent and inducing anesthesia.

Participants/Inclusion and exclusion criteria

Children aged 6 months to 5 years old in Class 1 and 2 of the American Anesthesiology Association will be included in the study.Children with known sensitivity to ketamine or midazolam, history of using narcotics, age less than 6 months, increased intracranial pressure, history of seizure, upper and lower respiratory tract infection, will be excluded.

Intervention groups

The group of midazolam (receiving 0.1 milligram per kilogram of midazolam produced by Tehran Chemistry Factory diluted with distilled water) and the ketamine group (1 milligram per kilogram of ketamine produced by Rotex medica diluted with distilled water)

Main outcome variables

The child's sedation when separating from the parents, the child's sedation during induction of anesthesia and child sedation in recovery room.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161022030421N3**
Registration date: **2019-06-15, 1398/03/25**
Registration timing: **prospective**

Last update: **2019-06-15, 1398/03/25**
Update count: **0**

Registration date

2019-06-15, 1398/03/25

Registrant information

Name

Marzieh Lak

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2640-01-21, 2018/11/01

Expected recruitment end date

2640-05-22, 2019/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of intravenous ketamine and midazolam as a premedication in children undergoing cochlear implantation at the time of separation from parents

Public title
Comparison of the effect of intravenous ketamine and midazolam as a premedication in children .
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children from 6 months to 5 years of age with ASA class I and II, candidate for cochlear implant
Exclusion criteria:
Children with known sensitivity to ketamine or midazolam, as well as history of taking psychiatric medications, age less than 6 months, increased ICP, brain tumor masses, history of seizure, upper and lower respiratory tract infection.
Age
From **6 months** old to **5 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned into two groups of midazolam and ketamine. The person who codes the drug, for example, may will allocate even numbers to ketamine and odd numbers to midazolam, or vice versa.
Blinding (investigator's opinion)
Double blinded
Blinding description
The medication will be prepared by a person in the volume of 5 cc and the drug code is written on it. Then another person who will not know the type of medicine will inject the drug into the child and fill out the questionnaire and record the drug code in the questionnaire.The child and parents will not be aware of the type of medicine.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Baqiyatallah University of Medical Sciences
Street address
Baqiyatallah University of Medical Science, Mollasadra Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1435915371
Approval date
2018-10-29, 1397/08/07
Ethics committee reference number
IR.BMSU.REC.1397.031

Health conditions studied

1

Description of health condition studied
Seduction of the chorus and dumb children
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
sedation when separating from parents
Timepoint
In the pre-operative room, when the child is separated from the parents
Method of measurement
Observe and filling the form of sedation anxiety score scale (SASS)

2

Description
Sedation of the child during induction of anesthesia
Timepoint
On the operating room bed, Induction of anesthesia
Method of measurement
Using the form of sedation anxiety score scale (SASS)

3

Description
Child sedation in recovery
Timepoint

From the child's arrival to the recovery until the release of the recovery

Method of measurement

Using PACU sedation score scale (PACUSSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (Midazolam): In this group, midazolam will be given with dose of one tenth of mg / kg of midazolamole in a 5-cc syringe and diluted into 5 cc distilled water. In pre-anesthetic room, the medicine will be injected intravenously, while the baby will be monitored for oxygenation.

Category

Rehabilitation

2

Description

Intervention group (Ketamin): In this group, ketamine with dose of 1 mg per kg will be injected into a 5-cc syringe and diluted into 5 cc distilled water. In pre-anesthetic room, the medicine will be injected intravenously, while the baby will be monitored for oxygenation.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Marzieh Lak

Street address

Baqiyatallah University of Medical Science, Mollasadra Street, Sheikh Bahaee Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Marzieh Lak

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after unidentifiable people.
When the data will become available and for how long
Starting 1 month after publication
To whom data/document is available
People working in academic institute
Under which criteria data/document could be used
For meta-analysis
From where data/document is obtainable
by Email
What processes are involved for a request to access data/document
By sending a request to the University Vice-Chancellor for Research and obtaining a license
Comments