Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of oral Midazolam and oral Ketamin as a sedative in pediatric patients need radiological imaging procedures, refer to emergency department of Zahedan khatam Al-Anbia hospital, years 2018-19: A randomized clinical trial for efficacy

Protocol summary

Study aim

Determination and comparison of sedation rate in children after oral administration of Midazolam and Ketamine, comparison of the patient's separation score from parents in two groups receiving oral Ketamine and Midazolam, determining and comparing the duration of patient's stay in the hospital in two groups receiving oral Midazolam and Ketamine Oral, Determine the duration to start the relaxation effect in oral Midazolam and Ketamine.

Design

Randomized clinical trial of Phase 3, double blinded, 100-person samples, with parallel groups of Midazolam and Ketamine

Settings and conduct

This double-blind clinical trial will be conducted at Khatam-ol-Anbia Hospital in Zahedan City. The patient and person who evaluates the symptoms of the patient, will be blinded to treatment group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 1 to 7 years who require diagnostic imaging. Exclusion criteria: Associated illnesses such as seizures, heart disease, respiratory disease, respiratory active infections, infectious diseases of the nervous system such as autism and ADHD, imaging duration more than 60 minutes, history of drug allergy to sedative medications, children who have received other sedative medications, taking antibiotics like Erythromycin, which causes metabolism problems, Parental dissatisfaction

Intervention groups

In one group, children received 0.5mg / kg of oral Midazolam and the second group received 5mg / kg of oral Ketamine with 20cc cherry juice given to the patient to improve the taste of the drug. After administering the drug, every 10 minutes (up to 30 minutes), the tranquility level in each group is ranked using the 5-point method and the 3 score is considered as a satisfactory and appropriate sedation level. After administration of the medication, the sedation level in each group will calculated using the same method.

Main outcome variables

Sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180708040396N1**
Registration date: **2018-07-15, 1397/04/24**
Registration timing: **prospective**

Last update: **2018-07-15, 1397/04/24**
Update count: **0**

Registration date

2018-07-15, 1397/04/24

Registrant information

Name

Mahjobeh Keikha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5744

Email address

mahjobehkeikha@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-07-22, 1397/04/31
Expected recruitment end date
2019-11-21, 1398/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of oral Midazolam and oral Ketamin as a sedative in pediatric patients need radiological imaging procedures, refer to emergency department of Zahedan khatam Al-Anbia hospital, years 2018-19: A randomized clinical trial for efficacy

Public title
Comparison of the effect of oral Midazolam and Ketamine as a sedative in children requiring radiologic action
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 1 to 7 years who require diagnostic imaging.
Exclusion criteria:
Concomitant illnesses such as seizures, heart disease, respiratory diseases and respiratory active infections Infections of the nervous system such as autism, ADHD The imaging time is longer than 60 minutes A history of drug allergy to sedative medicines Children who have received other sedative medications The use of Antibiotics like erythromycin, which causes metabolism problem Parental dissatisfaction
Age
From **1 year** old to **7 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Children will be divided into two groups. Given the fact that the method of randomization is by blocking method, here the 10-block blocks will randomly be replaced with how patients are placed in blocks. Each block will consist of 5 patients from each group. Due to the gradual entry of patients, a block will be selected first and a card will be selected accordingly, depending on which patient will be in the corresponding group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient and the person who evaluates the symptoms of the patient will be blinded to the treatment group. In other words, the participants will be satisfied with the entry into the research, but will be blinded on which treatment group they are going to be. Also, the data collection team that evaluates the outcomes will be blinded to the outcome of the treatment groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Zahedan University of Medical Sciences, Dr Hesabi sq., Daneshgah blvd.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2018-05-26, 1397/03/05
Ethics committee reference number
IR.ZAUMS.REC.1397.109

Health conditions studied

1

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

Primary outcomes

1

Description
Restlessness
Timepoint
After administering the drug every 10 minutes to 30 minutes, the tranquility level in each group is ranked using the 5-point method and the 3 score is considered as a satisfactory and appropriate sedation level. After administering the drug, the sedation level is grouped in

each group using the re-evaluation method.

Method of measurement

With a 5-degree scale from restless to sleep, calmness will be measured.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Midazolam - In this group, children received 0.5mg / kg 0.5 mg of Midazolam (using Midazolam 5 mg / ml) with twenty cc juice to improve the taste of the drug, is given to the patient by the glass.

Category

Treatment - Drugs

2

Description

Intervention group: Ketamine - In this group, children received 5 mg / kg of oral Ketamine (using doses of 50 mg per 10 ml) with twenty cc juice to improve the taste of the medicine, given to the patient by the glass.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al Anbia Hospital

Full name of responsible person

Zabih Allah Hashem Zahi

Street address

Khatam Al Anbia Hospital, Jam-e-jam blvd.

City

Zahedan

Province

Sistan-va-Balouchestan

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9815733169

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zabih1966@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Zahedan University of Medical Sciences, Dr Hesabi sq., Daneshgah blvd.

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Province

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Postal code

9816743463

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taheri@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Mahjobeh Keikha

Position

Resident of Emergency Medicine

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mahjobeh Keikha

Position

Resident of Emergency Medicine

Latest degree

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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

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

Only part of the information, such as the main outcome information, can be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will only be available to researchers in university and academia

Under which criteria data/document could be used

Only the use of data is allowed to the idea of future research.

From where data/document is obtainable

Referring to the university vice chancellor

What processes are involved for a request to access data/document

Data will be available after approval by the university's research director.

Comments