

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A Comparative study between midazolam ,dexmedetomidine and melatonin as oral premedication for pediatric sedation and ease of separation from their parents before anesthesia

Protocol summary

Study aim

A Comparative study between midazolam ,dexmedetomidine and melatonin as oral premedication for pediatric sedation and ease of separation from their parents before anesthesia

Design

This study is clinical trials and double blind.153 patients candidated elective surgery with 2 to 10 years in hospitals affiliated to Arak University of Medical Sciences will enter.

Settings and conduct

This study is clinical trials and double blind.153 patients candidated elective surgery with 2 to 10 years in hospitals affiliated to Arak University of Medical Sciences will enter.The patient is not aware of the treatment received.Participant and Analyzer are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 2 to 10 years, no history of allergies Dexmedetomidine and Midazolam and Melatonin, the absence of liver, kidney, heart and lung disorders, no use long-term anti seizure drug, lack of sleep disorder, lack of digestive disorders Exclusion criteria: Dissatisfied to participate in the study

Intervention groups

We divide patients in 3 groups randomly.We prescribe 0/5 milligram in kilogram in first group, 0/2 milligram in kilogram in second group and 2/5 micro gram in kilogram in third group.

Main outcome variables

pediatric sedation and ease of separation from their parents before anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N77**

Registration date: **2018-05-18, 1397/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-18, 1397/02/28**

Update count: **0**

Registration date

2018-05-18, 1397/02/28

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-11, 1396/12/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative study between midazolam

,dexmedetomidine and melatonin as oral premedication for pediatric sedation and ease of separation from their parents before anesthesia

Public title

A Comparative study between midazolam ,dexmedetomidine and melatonin as oral premedication for pediatric sedation and ease of separation from their parents before anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

2 to 10 years No history of allergies Dexmedetomidine and Midazolam and Melatonin The absence of liver, kidney, heart and lung disorders No use long-term anti seizure drug Lack of sleep disorder Lack of digestive disorders

Exclusion criteria:

Dissatisfied to participate in the study

Age

From **2 years** old to **10 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **153**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not aware of the treatment received.Participant and Analyzer are blind (double blind).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam

complex, Basij squre, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2018-03-04, 1396/12/13

Ethics committee reference number

IR.ARAKMU.REC.1396.313

Health conditions studied

1

Description of health condition studied

sedation

ICD-10 code

T88.52

ICD-10 code description

Failed moderate sedation during procedure

Primary outcomes

1

Description

separation from their parents

Timepoint

Before surgery

Method of measurement

sepration score

2

Description

sedation score

Timepoint

Before prescribing drugs, then when the child is separated from the parent

Method of measurement

sedation score

3

Description

blood pressure

Timepoint

every 5 minute in surgery

Method of measurement

Barometer

4

Description

heart rate

Timepoint

every 5 minute in surgery

Method of measurement

beat in minute

5

Description

Percent saturation of oxygen

Timepoint

every 5 minute in surgery

Method of measurement

Percent

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We prescribe 0/5 milligram in kilogram

Category

Treatment - Drugs

2

Description

Intervention group: We prescribe 0/2 milligram in kilogram .

Category

Treatment - Drugs

3

Description

Intervention group: We prescribe 2/5 micro gram in kilogram .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr Bijan Yazdi

Street address

Parastar square, Shahid Shirodi street

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+98 86 3222 2003

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yazdi@arakmu.ac.ir

2

Recruitment center

3

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Bijan Yazdi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Vice chancellor for research, Payambar azam complex, Basij squire, Sardasht, Arak

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arjmandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Hesamedin Modir
Position
Assistante professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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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

When we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Bijan Yazdi

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

They have to write letters to the professors and the university

Comments