Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative study of dexmedetomidine-fentanyl vs. midazolam-ketamine in sedation in children undergoing bone marrow biopsy

Protocol summary

Study aim
Comparative study of dexmedetomidine-fentanyl vs. midazolam-ketamine in sedation in children undergoing bone marrow biopsy

Design
This study is a single blind clinical trial with a control group performed on 70 patients. stratified block randomization will be used for randomization.

Settings and conduct
This study will be done at Mofid Children's Hospital in Tehran in patients who are candidates for bone marrow biopsy.Patients will be divided into two groups.The first group will receive 2 micrograms / kg of dexmedetomidin plus 1 microgram / kg of fentanyl, and the second group (intervention) will receive 1 mg / kg of ketamine plus 0.1 mg / kg of midazolam. Sedation Score , Mean arterial Blood pressure, Heart rate, immediately before prescribing, 2, 5, 10, 15 minutes after prescribing the drug will be recorded in two groups and compared with each other.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children 2 to 6 years of age have ASA I and ASA II classes that are candidates for bone marrow biopsy.Exclusion criteria: congenital heart disease, respiratory disease, productive cough, fever, wheezing or crackles , Refusal of parents to continue cooperating in the project.

Intervention groups
The control group will receive 0.1 mg / kg intrevenous midazolam plus 1 mg / kg intravenous ketamine.The intervention group will be given 1 microgram / kg of intravenous fentanyl plus 2 micrograms / kg of intravenous dexmedetomidine.

Main outcome variables
Sedation Score; Mean Arterial Pressure; Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160301026866N11**
Registration date: **2020-06-23, 1399/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-23, 1399/04/03**
Update count: **0**

Registration date
2020-06-23, 1399/04/03

Registrant information

Name
Amir Shafa

Name of organization / entity
Isfahan University of Medical Sciences, Imam hossein Hospital

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-07-20, 1399/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of dexmedetomidine-fentanyl vs.

midazolam-ketamine in sedation in children undergoing bone marrow biopsy

Public title
Comparative study of dexmedetomidine-fentanyl vs. midazolam-ketamine in sedation in children undergoing bone marrow biopsy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children 2 to 6 years of age ASA I and ASA II classes , bone marrow biopsy candidates
Exclusion criteria:
Congenital heart and respiratory disease productive cough fever wheezing or cracking in the lungs parental withdrawal from the project
Age
From **2 years** old to **6 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by method stratified block randomization.All blocks are the same size.The size of each block is 5 people.The first 5 people involved in intervention 1 are in block 1 and the second 5 people who are in the second intervention are in block 2. And so it repeats.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is single blind and Patients do not know how to be in groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences, Ethics comitte
Street address
Shahid Beheshti University of Medical Sciences, Yaman Ave, Chamran Highway,
City
Tehran
Province
Tehran
Postal code
1546815514
Approval date
2020-05-30, 1399/03/10
Ethics committee reference number
IR.SBMU.RETECH.REC.1399.138

Health conditions studied

1

Description of health condition studied
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sedation Score
Timepoint
Immediately before prescribing the drug, 2,5,10,15 minutes after drug administration
Method of measurement
Ramsay Scale

2

Description
Mean Arterial Blood pressure
Timepoint
Immediately before prescribing the drug, 2, 5 ,10,15 minutes after drug administration
Method of measurement
Anesthesia monitoring device

3

Description
Heart Rate
Timepoint
Immediately before prescribing the drug, 2, 5,10,15 minutes after drug administration
Method of measurement
Anesthesia monitoring device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Sedation with 2 micrograms / kg

fentanyl plus 2 micrograms / kg dexmedetomidine intravenously

Category

Treatment - Drugs

2

Description

Control group: sedation with 0.1 mg / kg midazolam plus 1 mg / kg ketamine intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Hospital

Full name of responsible person

Amir Shafa

Street address

Mofid Hospital, Shariati Ave

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1546815514

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zargi

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Amir Shafa

Position

Fellowship Residency

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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
All data can be shared after people have not been identified
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
Access is free for all researchers
Under which criteria data/document could be used
An official request should be sent from the research institute.
From where data/document is obtainable
Send email to Amir Shafa: shafa_amir@yahoo.com
What processes are involved for a request to access data/document
Request via email
Comments