Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

: A Comparative Study of the Effect of Dexmedmotidine and Midazolam on Prevention of Agitation Before Bone Marrow Aspiration and Bone Marrow Biopsy and Intracranial Chemo Therapy in Cancerous Children

Protocol summary

Study aim

A Comparative Study of the Effect of Dexmedmotidine and Midazolam on Prevention of Agitation Before Bone Marrow Aspiration and Bone Marrow Biopsy and Intracranial Chemo Therapy in Cancerous Children

Design

This study is a double-blind randomized trial that is the study phase 3 and block randomization method is used for randomization.

Settings and conduct

This study was a double-blind randomized clinical trial with parallel groups in which children aged 2 to 15 years who were candidates for bone marrow biopsy and aspiration procedures were divided into two identical groups: dexmedetomidine and midazolam and They are then compared for agitation and vital signs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- All children 2 to 15 years old who are candidates for biopsy and bone marrow aspiration or intrathecal chemotherapy. 2- Obtaining informed consent from the patient (parents) Conditions of non-entry: 1- Existence of contraindication of lumbar puncture 2- History of cardiopulmonary and renal disease 3- Existence of anatomical disorders in the patient's neck and spine

Intervention groups

Dexmedetomidine group: 45 children 2 to 15 years old who will receive a 5-minute intravenous infusion of dexmedetomidine at a dose of 2 micrograms per kilogram. Midazolam group: 45 children receiving a 5-minute intravenous midazolam injection at a dose of 0.2 mg / kg.

Main outcome variables

4-point sedation scale measured at 5, 10, 20, 30 minutes after drug injection. Respiratory rate per minute, measured at 5, 10, 20, 30 minutes after drug injection. Blood pressure is measured at 5, 10, 20, 30 minutes after drug injection. Oxygen saturation is measured at 5, 10, 20, 30 minutes after drug injection. Heart rate per minute measured at 5, 10, 20, 30 minutes after drug injection. .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045328N9**
Registration date: **2022-03-03, 1400/12/12**
Registration timing: **prospective**

Last update: **2022-03-03, 1400/12/12**
Update count: **0**

Registration date

2022-03-03, 1400/12/12

Registrant information

Name

Amin Haji seyyed hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-05, 1401/01/16

Expected recruitment end date

2022-07-07, 1401/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

: A Comparative Study of the Effect of Dexmedmotidine and Midazolam on Prevention of Agitation Before Bone Marrow Aspiration and Bone Marrow Biopsy and Intracranial Chemo Therapy in Cancerous Children

Public title

Comparison of the effect of dexmedetomidine and midazolam on the prevention of agitation before aspiration and bone marrow biopsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All children 2 to 15 years old who are candidates for bone marrow biopsy and aspiration or intrathecal chemotherapy. Obtaining informed consent from the patient (parents)

Exclusion criteria:

Contraindication of lumbar puncture History of cardiopulmonary and renal disease Existence of anatomical disorders in the patient's neck and spine

Age

From **2 years** old to **15 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are assigned to two intervention and control groups, respectively, based on the randomization sequence that will be generated beforehand. This sequence is unpredictable and its arrangement is completely random. Block randomization method with 8 blocks will be used to allocate samples. Thus, using block numerical random number generation software, a randomization sequence proportional to the sample size required for the two groups will be generated. Initially, all cases in which the two letters A and B can be arranged in blocks of 8 are produced. A block is then randomly selected from the blocks and the layout pattern in that block will be used to assign participants. This block will then be placed in the main container and another block will be selected again. All this will be done with software called Sealed Envelope. With this method, concealment will also be observed. The concept of concealment is to unpredictably assign individuals to groups. In fact, the researcher will not be able to predict which group the next person will be in.

Blinding (investigator's opinion)

Double blinded

Blinding description

Vials of the same volume are drawn into the same syringes, and the patient's participant and clinical caregiver (nurse) are unaware of its contents.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

Street address

Research Assistant, Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2021-07-18, 1400/04/27

Ethics committee reference number

IR.ARAKMU.REC.1400.105

Health conditions studied

1

Description of health condition studied

Agitation before aspiration and bone marrow biopsy

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

4-point sedation scale

Timepoint

4-point sedation scale measured at 5, 10, 20, 30 minutes after drug injection.

Method of measurement

4-point sedation scale include: Restlessness: 4 Awakening: 3 Sleepy: 2 Sleeping: 1. (Which are desirable

in this scale of 1st and 2nd degree.) This scale is measured based on the judgment of the doctor in the examination.

2

Description
Respiratory rate per minute
Timepoint
measured at 5, 10, 20, 30 minutes after drug injection
Method of measurement
Counting

3

Description
Blood pressure
Timepoint
measured at 5, 10, 20, 30 minutes after drug injection
Method of measurement
Barometer cuff

4

Description
Oxygen saturation
Timepoint
measured at 5, 10, 20, 30 minutes after drug injection
Method of measurement
Pulse oximetry

5

Description
Heart rate per minute
Timepoint
measured at 5, 10, 20, 30 minutes after drug injection
Method of measurement
Counting

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 45 children 2 to 15 years of age who receive a 5-minute intravenous infusion of 2 micrograms per kilogram of dexmedetomidine intravenously before performing a biopsy procedure and bone marrow aspiration or intrathecal chemotherapy.
Category
Treatment - Drugs

2

Description
Intervention group: Forty-five children will receive a 5-minute intravenous midazolam injection at a dose of 0.2 mg / kg before a biopsy procedure and bone marrow aspiration or intrathecal chemotherapy.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Amir Kabir Hospital
Full name of responsible person
Dr. Vahid Falahati
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Sponsors / Funding sources

1

Sponsor
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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
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. Vahid Falahati
Position
Associate professor
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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
After conducting this study and analytical studies on it, only a part of the data such as information about the main outcome and patient demographic information will be published to the researchers who do the necessary correspondence with the person in charge of this study.
When the data will become available and for how long
Access will be from 2022/4/20 to 2026/4/20 for 4 years.
To whom data/document is available
University researchers
Under which criteria data/document could be used
If there are any further questions
From where data/document is obtainable

Dr. Vahid Falahati

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

Letter writing should be done with professors and universities.

Comments