Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation and Comparison of the Effectiveness of General Anesthesia with Souffleran and Propofol on Nausea, Vomiting and Agitation after Bone Marrow Aspiration and Intrathecal Injection in Children with Cancer Referred to Bahrami Hospital.

Protocol summary

Study aim
Comparison of the Effect of General Anesthesia with Souffleran and Propofol on Nausea, Vomiting and Postoperative Agitation

Design
Phase 3 clinical trial with two Arm Parallel Group with 30 Patients , Triple Blind ,Randomised trial with Sampling Table

Settings and conduct
All Participants in the Operating Room of Bahrami Hospital Will Receive 35mg / kg of Fentanyl Before Induction of Anesthesia. In the Next Stage, the First Group Will Receive Induction of Anesthesia with 8% Sulfoflurane and the Second Group with 2 mg / kg Propofol. It should be Noted that the Continuation of Anesthesia in Both Groups will be Using Isoflurane Inhalation Gas. In the Studies, Vital Signs were Measured Once Before the Treatment and then every 5 Minutes During the Duration of the Anesthesia will be Registered. After Transferring Patients to the Recovery Room, the Amount of Post-Operative Nausea and Vomiting as well as the Recovery Time will be Masured and Recorded. After the Treatment Process, the Severity of Nausea and Vomiting, Agitation , Severity of Pain and Granistron Prescription will be Registered. The Forthcoming Study will be in the form of Triple Blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria :children Between 1 and 10 Years Old With Cancer Exclusion criteria: • Dissatisfaction • Lack of Proper Cooperation •History of Any Disease(Cardiovascular, Respiratory , Allergies)

Intervention groups
(1) Induction Group of Anesthesia Using Soufflore and (2) Group of Induction of Anesthesia with Use of Propofol.

Main outcome variables
Mean Arterial Pressure Heart Rate Severity of Nausea and Vomiting Agitation Rate Postoperative Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211206053305N1**
Registration date: **2022-10-10, 1401/07/18**
Registration timing: **retrospective**

Last update: **2022-10-10, 1401/07/18**
Update count: **0**

Registration date
2022-10-10, 1401/07/18

Registrant information

Name
Seyedehmahsa Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 5216 1764

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smahsahosseini1376@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-08-23, 1401/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation and Comparison of the Effectiveness of General Anesthesia with Souffleran and Propofol on Nausea, Vomiting and Agitation after Bone Marrow Aspiration and Intrathecal Injection in Children with Cancer Referred to Bahrami Hospital.

Public title
Evaluation of the Effect of Two Different Methods of Anesthesia on Pain and Nausea and Vomiting in Children with Cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All Children Between the Ages of 1 and 10 Have a Diagnosis of Cancer that Requires General Anesthesia for Intrathecal Injection and Bone Marrow Biopsy
Exclusion criteria:
Dissatisfaction of the Patient or her/his legal Guardian to Participate in the Study Lack of Proper Cooperation of the Patient or his/her legal Guardian History of Any Past or Present lung Disease or Involvement History of Past or Present Respiratory Distress History of Any Past or Present Cardiovascular Disease Simultaneous Involvement of Any Disorders leading to Nausea and Vomiting History of Any Drug Allergies, Allergies to Eggs, Soy History of Convulsion
Age
From **1 year** old to **10 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done using limited randomization method of block randomization type. The size of all the blocks is equal and in this two-group trial, the participants are assigned equally to two intervention and control groups of 15 people using blocks of 6. The randomization tool will be a random sequence generation software. In order to hide random allocation, non-transparent sealed envelopes with random sequence will be used. Each of the random sequences created is recorded on a card and the cards are placed in the envelopes in order. In order to maintain the random sequence, the outer surface of the envelopes is numbered in the same order.Finally, the lids of the envelopes are glued and placed in a box. At the time of the registration of the participants, according to the order of entry of the eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed. The person who created the random sequence will not be involved in other stages of the study, including the allocation of participants.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Blinding of the Type of Intervention Performed in Patients Will Be Done in the Data Collection Stage (lack of knowledge of the Examiner about the Intervention Group) and the Stage of Data Analysis (lack of knowledge of the Statistical Analyst of the Type of Intervention in Each Group). Therefore, the forthcoming Study will be in the form of Triple Blind .In this Way, the Patients are Children and their Parents Do Not know about the Study Group and do not know Which Group they are in. On the other hand, the Person who Collects the Information and Registers it in the Patient Information Sheet does not know the Patient Group, and on the third hand, the Person who Analyzes the Information also does not know the Patient Group because the Patients are Divided into 2 Groups: 1 and 2 and do not know the Name of the Group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
No 3, Yas dead end , Tavanir Ave , Valiasr Ave , Tehran
City
Tehran
Province
Tehran
Postal code
1434874983
Approval date
2021-06-23, 1400/04/02
Ethics committee reference number
IR.TUMS.CHMC.REC.1400.059

Health conditions studied

1

Description of health condition studied
Agitation and Nausea and Vomiting
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of Nausea and Vomiting
Timepoint
Post Operative Nausea and Vomiting will be Measured After Transferring Patients to the Recovery Room
Method of measurement
Examination

2

Description
Agitation
Timepoint
Pediatric Anesthesia Emergence Delirium Score will be Measured after Transferring Patients to the Recovery Room
Method of measurement
Pediatric Anesthesia Emergence Delirium Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Patients in the First Group will Receive 35 mg / kg Fentanyl Before Induction of Anesthesia. In the Next Step, They will be Induced Anesthesia by Receiving 8% Souffluran. Continuation of anesthesia is with isoflurane inhalation gas.
Category
Treatment - Drugs

2

Description
Intervention Group: Patients in the Second Group will Receive 35 mg / kg Fentanyl Before Induction of Anesthesia. In the Next Step, by Receiving Propofol at a Dose of 2 mg / kg, They will be Induced Under Anesthesia. Continuation of Anesthesia is with Isoflurane Inhalation Gas.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahrami Hospital
Full name of responsible person
Seyedeh Mahsa Hosseini
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Damavand St , Shahid Kiai St (Qasem Abad), Bahrami Children's Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Akbar Fotoohi
Street address
Sixth floor, Deputy of Research and Technology, Central Organization of the University , Quds Street ,Keshavarz Blv , Tehran
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Seyedeh Mahsa Hosseini
Position
Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available