Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of safety and efficacy of propofol/fentanyl and midazolam/fentanyl for procedural sedation

Protocol summary

Study aim

This study is designed to compare the safety and efficacy of propofol/fentanyl versus midazolam/fentanyl combinations for procedural sedation in the emergency department of Mofid Children’s Hospital.

Design

This is a randomized, single-blind, parallel-group, phase II clinical trial without a control group, involving 84 patients. Randomization will be carried out using stratified block randomization.

Settings and conduct

This is a randomized, single-blind clinical trial designed to compare the safety and efficacy of two drug combinations (propofol/fentanyl and midazolam/fentanyl) for procedural sedation in the emergency department of Mofid Children’s Hospital. Single-blinding means that participants (children and their parents) will be unaware of the drug combination being administered.

Participants/Inclusion and exclusion criteria

The study population will include all children aged 3 months to 18 years who are referred to the emergency department of Mofid Children’s Hospital and require procedural sedation. Children with hemodynamic instability, a history of cardiac diseases, known allergies to the study drugs, sensitivity to eggs or soy, and those classified as ASA physical status 5 (high anesthesia risk) will be excluded from the study.

Intervention groups

Patients will be randomly assigned to one of two groups: propofol/fentanyl or midazolam/fentanyl. In the propofol/fentanyl group, due to the onset time of the medications, intravenous fentanyl (1–2 µg/kg) will be administered first, followed by slow intravenous injection of propofol (1–2 mg/kg). In the midazolam/fentanyl group, intravenous midazolam (0.05–0.1 mg/kg) will be administered first, followed by slow intravenous injection of fentanyl (1–2 µg/kg).

Main outcome variables

1- Successful completion of the procedure 2- Recovery time 3- Procedural distress 4- Depth of sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250525065887N1**
Registration date: **2025-05-28, 1404/03/07**
Registration timing: **prospective**

Last update: **2025-05-28, 1404/03/07**
Update count: **0**

Registration date

2025-05-28, 1404/03/07

Registrant information

Name

Kourosh Soltaniyeh Zanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2290 4603

Email address

kouroshsoltaniye@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-22, 1404/04/01

Expected recruitment end date

2025-09-21, 1404/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of safety and efficacy of propofol/fentanyl and midazolam/fentanyl for procedural sedation

Public title
Comparison of safety and efficacy of propofol/fentanyl in pediatrics emergency department

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 3 months to 18 years who are referred to the emergency department of Mofid Children's Hospital Patients who require procedural sedation

Exclusion criteria:
Patients with hemodynamic instability Patients with a history of cardiac diseases Children with known allergies to the study medications Children with allergies to eggs or soy Children classified as ASA physical status class 5 (high anesthesia risk)

Age
From **3 months** old to **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method used in this study will be stratified block randomization. Patients will be stratified based on key characteristics such as age, gender, and ASA, and then randomly assigned to study groups using a block size of 4, generated by random allocation software. The random sequence will be created using a random number generator within the software, and the allocation list will be prepared in advance by an independent person not involved in the study implementation or outcome assessment. For allocation concealment, sealed, opaque, and sequentially numbered envelopes will be used. These envelopes will be opened only by the person enrolling the patient, right at the point of assignment.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be a single-blind trial. In this context, single-blinding means that the participants (patients and their parents) will not be aware of the specific drug combination administered (either propofol/fentanyl or midazolam/fentanyl). Due to the visible differences between the drugs and the necessity of ensuring medication safety, the administering physician will be aware of the drug type. However, the responsibility for evaluating outcome variables such as pain, distress, depth of sedation, and documentation of adverse events will lie with an independent observer (a trained nurse) who will be blinded to the group allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd, Velenjac,Tehran, Iran.

City
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Postal code
1985717443

Approval date
2025-04-29, 1404/02/09

Ethics committee reference number
IR.SBMU.MSP.REC.1404.087

Health conditions studied

1

Description of health condition studied
Patients requiring LP

ICD-10 code
G97.1

ICD-10 code description
Other reaction to spinal and lumbar puncture

2

Description of health condition studied
Patients requiring intubation

ICD-10 code
J98.9

ICD-10 code description
Respiratory disorder, unspecified

3

Description of health condition studied
Patients with limb dislocation or fracture

ICD-10 code
T14.3

ICD-10 code description

Dislocation, sprain and strain of unspecified body region

Primary outcomes

1

Description
Successful completion of the procedure
Timepoint
After the intervention
Method of measurement
"Success or failure of the procedure (which may include suturing, limb casting, lumbar puncture, intubation, etc.)"

2

Description
Patient recovery time after sedation
Timepoint
After the intervention
Method of measurement
Measurement of the time interval between the administration of the last dose of sedative medication and the point at which the patient is deemed ready for discharge from the emergency department based on post-sedation discharge criteria.

3

Description
Procedural distress
Timepoint
After the intervention
Method of measurement
To assess procedural distress in patients, the Observational Scale of Behavioral Distress (OSBD) will be used by an independent observer (a trained nurse from the emergency department). This scale is utilized to evaluate the level of behavioral distress in children under 18 years of age undergoing medical interventions.

4

Description
Depth of sedation
Timepoint
After the intervention
Method of measurement
The Ramsay Sedation Scale will be used to assess the depth of sedation.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first intervention group, intravenous fentanyl (1–2 micrograms per kilogram) will be administered first, followed by slow intravenous administration of propofol (1–2 milligrams per kilogram). If the procedure is prolonged or if analgesia or sedation is inadequate, additional doses of fentanyl (1 microgram per kilogram) and propofol (0.5 milligrams per kilogram) will be administered.
Category
Treatment - Drugs

2

Description
Intervention group: In the second intervention group, intravenous midazolam (0.05–0.1 milligrams per kilogram) will be administered first, followed by slow intravenous administration of fentanyl (1–2 micrograms per kilogram). If the procedure is prolonged or if analgesia or sedation is inadequate, additional doses of fentanyl (1 microgram per kilogram) and midazolam (0.05 milligrams per kilogram) will be administered.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emergency department, Mofid Children's Hospital
Full name of responsible person
Kourosh Soltaniyeh Zanjani
Street address
Mofid Children's Hospital, Shariati Ave, Tehran, Iran
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1546815514
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kouroshsoltaniye@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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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

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

Kourosh Soltaniyeh Zanjani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Emergency Medicine

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Mofid Children's Hospital, Shariati Ave, Tehran, Iran.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Assistant Professor

Latest degree

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Person responsible for updating data

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Name of organization / entity

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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 demographic and clinical data collected from patients in the present study will be shared after de-identification.

When the data will become available and for how long

Access to the data will begin following the publication of the study results in the form of a scientific article.

To whom data/document is available

The data will be openly accessible to the public.

Under which criteria data/document could be used

Data aggregation for multicenter studies will be possible upon request to the clinical trial coordinator (Dr. Kourosh Soltaniyeh Zanjani) and approval by the research team.

From where data/document is obtainable

To access the study data, please contact the clinical trial coordinator, Dr. Kourosh Soltaniyeh Zanjani, via email at kouroshsoltaniye@gmail.com.

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

Any requests regarding the research or industrial use of the data will be reviewed by the clinical trial coordinator and the research team and will be answered within seven working days.

Comments