

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative evaluation of the effect of the two combinations of Propofol-Ketamine and Propofol-Sufentanil on sedation and analgesia during painful diagnostic procedures in children with hematologic malignancies

Protocol summary

Study aim

Comparison of the effects of two combinations of propofol-ketamine and propofol-sufentanil on sedation and analgesia during painful procedures in children with hematologic malignancies.

Design

Double-blind clinical trial with parallel groups using random allocation software, patients will be included in two groups of 35 for treatment intervention.

Settings and conduct

After approval by the Ethics Committee of Isfahan University of Medical Sciences, 102 children with blood malignancies in Omid Hospital are scheduled for 1396. In this patient study, the pediatric hematologist and data collector are unaware of the grouping and drugs studied.

Participants/Inclusion and exclusion criteria

Children 1 to 14 years old with Hematologic malignancy, Acute lymphoblastic leukemia
Inclusion criteria: Children aged 1 to 14 years with Hematologic malignancy
Exclusion criteria: injury to the head Cardiovascular disease, Respiratory disease, Liver disease, Epilepsy, seizure, or neurological disorders
Use of analgesic or sedative medications before surgery
Chronic pain syndromes

Intervention groups

Propofol-sufentanil (PS) and Propofol-Ketamine (PK) are grouped. In the PK group, propofol 1 mg / kg at concentrations of 5 mg / cc and ketamine 0/3 mg / kg at a concentration of 5 mg / cc and in the ps group sufentanil 0 / 5mic / kg and propofol 1mg / kg at a concentration of 5mg / cc, the volume of the drug compounds to 20 cc, and the infusion of drugs continues to reach the appropriate sedation level.

Main outcome variables

Sedation level; Analgesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170809035601N9**

Registration date: **2018-10-23, 1397/08/01**

Registration timing: **retrospective**

Last update: **2018-10-23, 1397/08/01**

Update count: **0**

Registration date

2018-10-23, 1397/08/01

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 2105

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-04-05, 1396/01/16

Actual recruitment end date

2018-02-09, 1396/11/20

Trial completion date

2018-02-09, 1396/11/20

Scientific title

Comparative evaluation of the effect of the two combinations of Propofol-Ketamine and Propofol-Sufentanil on sedation and analgesia during painful diagnostic procedures in children with hematologic malignancies

Public title

Effect of propofol-ketamine and propofol-sufentanil on sedation and analgesia in painful diagnostic methods in children with hematological malignancies

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 1 to 14 years Hematologic malignancies
Acute lymphoblastic leukemia

Exclusion criteria:

A recent trauma to the head Cardiovascular, pulmonary, or liver diseases Epilepsy, seizure or neurological disorder Use of analgesic or sedative medications before surgery Chronic pain syndrome History of allergy to the drugs studied

Age

From **1 year** old to **14 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients in the operating room are divided into two groups by random allocation software (Random allocation software). The first group propofol, ketamine, and the second group will receive propofol, sufentanil

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, participants, the main investigator and the person collecting data are unaware of the grouping of patients and the type of medication.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar jerib Blvd

City

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Province

Isfahan

Postal code

8174173461

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

lr.mui.rec.1396.3.629

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukaemia [ALL]

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukemia [ALL]

Primary outcomes

1

Description

sedation level

Timepoint

During procedure

Method of measurement

university of michigan sedation scale

Secondary outcomes

1

Description

Analgesia

Timepoint

During procedure

Method of measurement

Universal Pain Assessment Tool

Intervention groups

1

Description

In the PK group, propofol 1mg / kg with 5mg / cc of

vectamine (0 / 3mg / kg) with 5mg / cc concentration of drug was added to 20 cc and the infusion of the drug continued to reach the appropriate sedation level.

Category

Treatment - Drugs

2**Description**

Control group: In the PS group, sufentanil 0.5mic / kg and propofol 1mg / kg at a concentration of 5mg / cc, the volume of the drug was added to 20 cc. Infusion of the drug compound continues to flush with the appropriate sedation level:

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Omid Medical Center

Full name of responsible person

Hamidreza Shetabi

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Khayyam Street, Kay Nahr Farshad Hospital, Seyed Alshohada Hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza shetabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

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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

The data include the amount of sedation and pain level and hemodynamic indicators and complications in both groups after the intervention of unrecognizable people sharing.

When the data will become available and for how long

Beginning 6 months after the publication access

To whom data/document is available

Academic and health researchers

Under which criteria data/document could be used

Used for research and therapeutic

From where data/document is obtainable

Email responsible for public accountability study:
hamidshetabi@med.mui.ac.ir

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

If access upon request via e-mail will be sent within a maximum 1 month

Comments