

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparative evaluation of the effect of propofol_ketamine and propofol_remifentanyl for deep sedation and analgesia during painful procedures in 6 month to 14 year old children with acute lymphoblastic leukemia

Protocol summary

Summary

Abstract Objective: Comparing the effectiveness of two drug combinations of Propofol-Ketamine and Propofol-Remifentanyl in children with acute lymphoblastic leukemia under bone marrow aspiration or biopsy and lumbar puncture. **Methods:** In a clinical trial, 81 children of 6 months to 14 years old with acute lymphoblastic leukemia who were candidates for lumbar puncture, bone marrow aspiration or biopsy were randomly divided into two groups of receiving Propofol-Ketamine and receiving Propofol-Remifentanyl. In each group, hemodynamic indices, sedation, side effects, the onset of effectiveness and duration of remaining in the recovery room were measured and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080935601N1**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Isfahan University of Medical Sciences

Expected recruitment start date

2016-09-19, 1395/06/29

Expected recruitment end date

2017-02-13, 1395/11/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the effect of propofol_ketamine and propofol_remifentanyl for deep sedation and analgesia during painful procedures in 6 month to 14 year old children with acute lymphoblastic leukemia

Public title

The effect of propofol_ketamine and propofol_remifentanyl for deep sedation and analgesia during painful procedures in 6 month to 14 year old children with acute lymphoblastic leukemia in sayedoshohada Medical Center in Isfahan in 2016.

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria were included, Children aged between Six months to fourteen years old with

Hematologic Malignancies (such as acute lymphocytic leukemia) were candidates for painful intervention Lumbar Puncture; Bone marrow aspiration/Biopsy. Non-entry criteria include patients with head trauma; High intraocular pressure (IOP); or High intracranial pressure (ICP); cardiovascular or repertory or liver diseases; epilepsy or history of seizure; Neurological disorder ;tumor or metastasis of the brain; usage of analgesic or sedative drugs in before intervention; chronic pain syndrome; and not having to participate in the study; history of allergy or allergic reaction to Our study drugs Excluded criteria include any complications during intervention that causes the anesthetic program to change

Age

From **6 months** old to **14 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **81**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences

City

isfahan

Postal code

Approval date

2016-09-19, 1395/06/29

Ethics committee reference number

IR.mui.rec.1395.3.462

Health conditions studied

1

Description of health condition studied

Acute lymphoblastic leukaemia [ALL]

ICD-10 code

C91.0

ICD-10 code description

This code should only be used for T-cell and B-cell precursor leukaemia

Primary outcomes

1

Description

Sedation Level

Timepoint

During Procedure

Method of measurement

University of Michigan Sedation Scale (UMSS)

2

Description

Analgesia

Timepoint

During Procidure

Method of measurement

Universal Pain Assessment Tool (UPAT)

Secondary outcomes

1

Description

Hemodynamic changes (Heart rate , Systolic and Diastolic blood pressure, Mean atria pressure)

Timepoint

Before And Every 5 minutes during the procedure and Every 10 minutes in recovery

Method of measurement

Cardiac monitoring and automatic blood pressure monitoring

2

Description

Arterial oxygen saturation

Timepoint

Before and every 5 minutes during the procedure and Every 10 minutes in recovery

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Group 1 Propofol Ketamine (PK) Syringes No. 1, 2 and 3 containing propofol at a concentration of 1 mg per cc, ketamine with a concentration of 0.3 mg per cc, and

normal saline (as placebo) 1 cc per kilogram of weight from syringes 1 and 2 at the start of sedation and before prep and drep Syringe number 3 was injected.

Category

Treatment - Drugs

2**Description**

Group II propofol remifentanyl (PR) syringe number 4, containing propofol at a concentration of 1.5 mg / kg, syringe number 5 containing remifentanyl at a concentration of 1mcg / kg and syringe number 6 normal saline (as a placebo) of 1 cc/kg , Syringes 4 and 5 were injected at the start of sedation and before the prep and drep, the syringe 6 was injected

Category

Treatment - Drugs

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

Seyed Shahada Hospital in Isfahan

Full name of responsible person

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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**

Isfahan 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

Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty