Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative evaluation of the effect of propofol_ketamine and propofol_remifentanil 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-Remifentanil 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-Remifentanil. 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
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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_remifentanil 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_remifentanil 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 leukeamia

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 remifentanil (PR) syringe number 4, containing propofol at a concentration of 1.5 mg / kg, syringe number 5 containing remifentanil 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

Hamidreza Shetabi

Street address

Khayyam Street, Kay Nahr Farshad Hospital, Seyed Alshohada Hospital

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Nejatbakhsh DR

Street address

Hezar jerib , Isfahan University of Medical Sciences

City

Isfahan

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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Full name of responsible person

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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