Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of sedative and analgesic effects of ketamine-propofol and ketamine-sufentanil during bone marrow aspiration and lumbar Puncture in children

Protocol summary

Study aim

1. Determination and comparison of the average level of sedation (UMSS) studied in both groups during the procedure 2. Determination and comparison of the average intensity of pain (VAS) in the two study groups during the procedure 3. Determination and comparison of the average mean arterial pressure in the two groups before induction, during the procedure and recovery. 4. Determination and comparison of the average oxygen saturation in the two groups before induction, during and at the end of the recovery procedure. 5. Determination and comparison of the two groups in mean heart rate before induction, during and at the end of the procedure and recovery. 6. Determination and comparison of the onset of sedation in the two study groups. 7. Determination and comparison of the mean recovery time in the two study groups.

Design

Parallel group, double-blind clinical trial with the random numbers using two groups of 34 patients selected for therapeutic intervention

Settings and conduct

Double-blind study in which patients, pediatric hematologists and colleagues used data collected were not aware of the medications and is conducted at omid Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria:children between 6 month and 14 years old Candidate for bone marrow aspiration and lumbar Puncture Exclusion criteria:Hypersensitivity or allergic reaction to any medication regimen The use of analgesic and anesthetic in the past

Intervention groups

Intervention group: Group 1 (propofol-ketamine) 1 mg / kg propofol plus 0.3mg / kg ketamine were injected doubled Intervention group: Group 2 (ketamine-sufentanil) 1mg / kg ketamine with 0.1mic / kg sufentanil were injected doubled

Main outcome variables

Compare the level of sedation and pain in both groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170809035601N6**
Registration date: **2018-07-18, 1397/04/27**
Registration timing: **retrospective**

Last update: **2018-07-18, 1397/04/27**
Update count: **0**

Registration date

2018-07-18, 1397/04/27

Registrant information

Name
Hamidreza Shetabi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 31 3668 2105
Email address
hamidshetabi@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

2016-03-20, 1395/01/01

Actual recruitment end date
2017-03-21, 1396/01/01
Trial completion date
empty

Scientific title
Comparison of sedative and analgesic effects of ketamine-propofol and ketamine-sufentanil during bone marrow aspiration and lumbar Puncture in children

Public title
analgesic effects of ketamine-propofol and ketamine-sufentanil
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
children between 6 month and 14 years old Candid bone marrow aspiration and lumbar Puncture
Exclusion criteria:
Hypersensitivity or allergic reaction to any medication regimen The use of analgesic and anesthetic ago Cardiovascular disease, respiratory disease, liver disease, epilepsy or a history of seizures, neurological disorders, brain tumor or metastasis. There are chronic pain syndromes. Head injuries
Age
From **6 months** old to **14 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **68**
Actual sample size reached: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
With the arrival of the patient to the operating room, randomly block (permuted block randomization) with 4 blocks each divided into 2 groups.The first group recipient will ketamine-propofol and the second group recipient will ketamine-sufentanil
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and pediatric hematologists and Fellow collecting information were not aware of the medications.
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
hezar jarib
City
isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2016-08-15, 1395/05/25
Ethics committee reference number
IR.MUI.REC1395.3.643

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 (UMSS)

2

Description
Analgesia
Timepoint
During Procedure
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 during the procedure and recovery time

Method of measurement

Cardiac monitoring and automatic blood pressure monitoring

2

Description

Arterial oxygen saturation

Timepoint

Before and during the procedure and recovery time

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Intervention group: Group 1 (propofol-ketamine) 1 mg / kg propofol plus 0.3mg / kg ketamine were injected doubled

Category

Treatment - Drugs

2

Description

Intervention group: Group 2 (ketamine-sufentanil) 1mg / kg ketamine with 0.1mic / kg sufentanil were injected doubled

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

omid Hospital in Isfahan

Full name of responsible person

Hamidreza Shetabi

Street address

Khayyam Street, Kay Nahr Farshadi,omid Hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Nejatbakhsh DR

Street address

Hezar jerib , Isfahan University of Medical Sciences

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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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Person responsible for scientific inquiries

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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

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 researchers and health

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@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