

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Nitrous Oxide for propofol requirement in painful procedures in pediatric oncology unit

Protocol summary

Summary

The aim of this study is to evaluate the effect of N2O on the required dose of propofol in creating the perfect sedation for painful procedures in children. The first, 88 children who are candidates for bone marrow aspiration, are randomly divided into 2 groups. In Group I, combination of midazolam 0/03 mg / kg and fentanyl 1 µg / kg and ketamine 1 mg / kg and propofol 1 mg / kg are injecting intravenously. In Group II ,combination of midazolam 0/03 mg / kg and fentanyl 1 µg / kg and ketamine 1 mg / kg and propofol 1 mg / kg are injecting intravenously and from 2 minutes before the start of the procedure until the end of the procedure the patient is used to ventilate the gas entonox. In both groups, the aim is achieve to sedation Level 4 is based on Ramsay sedation scale, if necessary, every 1 minute ,propofol 1 mg / kg to be administered intravenously. The SpO2 and HR record before drug administration, immediately before the start of the procedure, at the beginning of the procedure, at the end of the procedure. The satisfaction will be evaluated and documented, by the physician performing the procedure and help nurse him by VAS (0-10). In addition to ,age, weight, duration of procedure, recovery time, the prescription drugs for each patient and the occurrence of any complication record.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090513364N2**

Registration date: **2016-12-05, 1395/09/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-05, 1395/09/15

Registrant information

Name

Mehrdad Taheri

Name of organization / entity

Shahid Beheshti University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Shahid Beheshti University Of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2015-11-01, 1394/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Nitrous Oxide for propofol requirement in painful procedures in pediatric oncology unit

Public title

Doing sedation in paediatric

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing bone marrow biopsy (the first turn) exclusion criteria: History of asthma; Catching common cold; detection of any complications during the procedure (apnea; %90 ≥

SPo2;Bradycardia > %30 of baseline);Doing any previous procedure with sedation;Parent discontent;Not fasting;History of hypersensitivity to any of the drugs

Age

From **1 day** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research and Technology, Shahid Beheshti University Of Medical Sciences

Street address

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway, Shahid Beheshti University Of Medical Sciences

City

tehran

Postal code

198396-3113

Approval date

2014-10-26, 1393/08/04

Ethics committee reference number

sbmu.rec.1393.363

Health conditions studied

1

Description of health condition studied

AML

ICD-10 code

C92.0

ICD-10 code description

Acute myeloblastic leukaemia [AML]

2

Description of health condition studied

ALL

ICD-10 code

C91.0

ICD-10 code description

Acute lymphoblastic leukaemia [ALL]

Primary outcomes

1

Description

sedation scale

Timepoint

1 minute

Method of measurement

Ramsay sedation scale

Secondary outcomes

1

Description

Recovery time

Timepoint

After the procedure

Method of measurement

minute

2

Description

SpO2

Timepoint

Before administration of drugs - immediately before the procedure - at the beginning of the procedure - at the end of the procedure

Method of measurement

Pulse Oximeter

3

Description

heart rate

Timepoint

Before administration of drugs - immediately before the procedure - at the beginning of the procedure - at the end of the procedure

Method of measurement

Pulse Oximeter

4

Description

Physician satisfaction

Timepoint

During the procedure

Method of measurement

VAS (10-0)

5

Description

Nurse satisfaction

Timepoint

During the procedure

Method of measurement

VAS (10-0)

Intervention groups

1

Description

In the control group, combination of midazolam 0/03 mg / kg and fentanyl 1 µg / kg and ketamine 1 mg / kg and propofol 1 mg / kg are injecting intravenously.

Category

Treatment - Drugs

2

Description

In the study group, combination of midazolam 0/03 mg / kg and fentanyl 1 µg / kg and ketamine 1 mg / kg and propofol 1 mg / kg are injecting intravenously and the patients are ventilated with entonox, 2 minutes before the start of the procedure until the end of the procedure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Mehrdad Taheri

Street address

Madani Ave

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Shahid Beheshti University Of Medical Sciences

Full name of responsible person

Mostafa Alavimoghaddam

Street address

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway, Shahid Beheshti University Of Medical Sciences

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tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology, Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehrdad Taheri

Position

assistant professor of anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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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