

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effect of Isoflurane and Propofol on prevention of emergence agitation in children under 3 having probing surgery

Protocol summary

Study aim

Comparison of the effect of isoflurane with propofol to reduce postoperative agitation for children under three years after probing surgery

Design

Clinical trial with control group, with parallel groups, double-blind, on 108 patients, patients are divided into two groups of intervention and control based on a random table. The blocking method is divided into two groups using the sealedenvelop.com website.

Settings and conduct

Children under three years of age referred to Khatam Al-Anbia Eye Specialized Hospital of Mashhad University of Medical Sciences, who are admitted for outpatient probing surgery. The method of concealment will be to use sealed, opaque envelopes

Participants/Inclusion and exclusion criteria

Inclusion criteria: All children under three years old referred to Khatam Al-Anbia Hospital in Mashhad who have outpatient probing Exclusion criteria: Children with underlying psychiatric disorders, Children with underlying illness, Seizure, Parental dissatisfaction, Drug allergy

Intervention groups

The anesthesia intervention group was controlled with intravenous propofol at a dose of 50 to 100 µg / kg and the control group was anesthetized with 2.5% isoflurane.

Main outcome variables

PROPOFOL,ISOFLURAN,REDUCE POST OPERATIVE AGITATHION

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210525051394N1**

Registration date: **2021-06-10, 1400/03/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-10, 1400/03/20**

Update count: **0**

Registration date

2021-06-10, 1400/03/20

Registrant information

Name

Hamideh Zarezadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5525 4480

Email address

zarezadehh971@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-06, 1400/03/16

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Isoflurane and Propofol on prevention of emergence agitation in children under 3 having probing surgery

Public title

Comparison of the effect of Isoflurane and Propofol on prevention of emergence agitation in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
All children under three years old referred to Khatam Al-Anbia Hospital in Mashhad having probing surgery

Exclusion criteria:
Children with underlying psychiatric disorder
Children with underlying disease
Convulsions
Dissatisfaction of parents
Drug allergy

Age
From **30 days** old to **3 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
The blocking method is divided into two groups using the sealedenvelop.com website

Blinding (investigator's opinion)
Double blinded

Blinding description
.The method of concealment will be to use sealed, opaque envelopes . Due to the fact that patients are anesthetized, they are unaware of the type of medicine used and have been blinded. The data analyst is also unaware of the assigned groups at the time of analysis.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of medical sciences

Street address

Medical school, Mashhad university of medical sciences, Azadi sq.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2021-05-30, 1400/03/09

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.083

Health conditions studied

1

Description of health condition studied

agitation

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

Severity of agitation

Timepoint

preoperative child evaluathion,postoperative and recovery
child severity agitathion evaluathion

Method of measurement

Richmond Sedation-Agitation Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Maintenance Anesthesia with hypnotic intravenous drug (propofol) at a dose of 50 to 100 µg / kg at interoperation time

Category

Prevention

2

Description

Control group: Maintenance Anesthesia with inhalathion anesthetic (isoflurane)2.5% at interoperation time

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al anbia hospihal university of mashhad

Full name of responsible person

zarezadehhamideh

Street address

No.55,Ordibehesht Ave,seyed mortaza Blvd,Kashmar Town

City
Mashhad
Province
Razavi Khorasan
Postal code
9671983957
Phone
+98 51 5523 5987
Email
zarezadehh971@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Tafaghodi mohsen
Street address
Ghorayshi Bil.Danehgah AVE
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3841 1538
Fax
+98 51 3843 0249
Email
tafaghodim@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Hamideh Zarezadeh
Position
Resident

Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
No.55,Ordibehesht Ave,seyed mortazaBlv
City
Kashmar
Province
Razavi Khorasan
Postal code
9671983957
Phone
+98 51 5525 4480
Fax
Email
zarezadehh971@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamideh Zarezadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
NO .55 .Aveordibehesht.Blvd seyed morteza
City
Kashmar
Province
Razavi Khorasan
Postal code
9671983957
Phone
+98 51 5525 4480
Fax
Email
zarezadehh971@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamideh Zarezadeh
Position
Resident
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City

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Phone

+98 51 5525 4480

Fax

Email

zarezadehh971@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available