

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effectiveness of pharmacological and non-pharmacological methods of reducing pain in retinopathy of prematurity examination

Protocol summary

Study aim

The practical purpose of this study is to reduce the possible side effects of the drugs used for the examination and increase the satisfaction of doctors by using appropriate analgesia methods during the ROP examination in addition to controlling the pain of the baby.

Design

This study, which is a double blind randomized control trial, will be conducted on 300 premature babies born and hospitalized in the NICU of Mahdiah Hospitals. At first, the informed consent form is given to the parents about the need and method of treatment, and after the necessary explanations and acceptance of the condition of the newborns, the candidates for eye examination enter the study.

Settings and conduct

Premature babies born with retinopathy are referred to Mahdiah Hospital within 5 months. This study will be conducted on 300 premature babies who were born and hospitalized in the NICU department. At first, the informed consent form is given to the parents about the need and method of treatment, and after the necessary explanations and acceptance of the condition, newborns candidates for eye examination enter the study.

Participants/Inclusion and exclusion criteria

The inclusion criteria include being hemodynamically stable and alert and able to tolerate oral sucrose 25%, at least one hour has passed since feeding, and the examination will be done before the next meal. Exclusion criteria include the baby of an addict mother, the use of sedative drugs before the examination, connection to a ventilator.

Intervention groups

Investigating the best and most effective pharmacological and non-pharmacological methods in reducing the eye examination pain of premature babies

born with ROP referred to Mahdiah Hospital within a period of 5 months.

Main outcome variables

Investigating the best and most effective pharmacological and non-pharmacological methods in reducing eye examination pain in premature babies with ROP.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211225053512N1**

Registration date: **2022-12-07, 1401/09/16**

Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**

Update count: **0**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name

Hamed Razi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 7021

Email address

razihamed50@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-19, 1401/09/28

Expected recruitment end date

2023-06-17, 1402/03/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of pharmacological and non-pharmacological methods of reducing pain in retinopathy of prematurity examination

Public title

Comparison of the effectiveness of pharmacological and non-pharmacological methods of reducing pain in retinopathy of prematurity examination

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Be hemodynamically stable Be alert And be able to tolerate 25% oral sucrose At least one hour has passed since the feeding The examination will also be done before the next meal

Exclusion criteria:

The baby of an addicted mother Taking sedative before examination Connected to the ventilator

Age

To 37 months old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: 300

Randomization (investigator's opinion)

Randomized

Randomization description

Random sampling based on the table of random numbers (at least 100 babies in each group). Allocation of patients in two groups was done by random block allocation method. The allocation sequence was generated using the free web-based system <https://www.sealedenvelope.com/>. To produce the sequence, the number of subjects in each block is 6 and 4, and letters A are for the intervention group and letters B are considered for the control group. Finally, 200 samples (24 blocks of 6 and 14 blocks of 4) have been produced in two groups A and B.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, Double Blinde Randomized Control Trial (double blind clinical trial), We decided to put eligible

infants in three groups of ketamine and fentanyl and non-pharmacological methods and compare their effectiveness in preventing pain. At least 100 babies in each group are included in the study based on the inclusion criteria and are randomly assigned to three treatment groups. Then, treatment groups are compared based on PIPP (premature infant pain index) which is measured by someone other than a nurse.

Placebo

Not used

Assignment

Parallel

Other design features

According to the definition of the World Health Organization, babies who are born before the 37th week from the first day of the last menstrual period are considered premature.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice President of Research and Technology Shahid Beheshti University of Medical Sciences.

Street address

Mahdieh Hospital., Shahid Rajabnia Street., Shishagar Alley., Fadaian Islam Street., Shush Street., Tehran., Iran

City

Tehran

Province

Tehran

Postal code

1185817311

Approval date

2022-04-25, 1401/02/05

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.037

Health conditions studied**1****Description of health condition studied**

Pain reduction in the eye examination of premature babies.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Gestational age

Timepoint

After the examination, the vital signs are monitored for 24 hours.

Method of measurement

Premature infant pain profile

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The non-pharmacological group of SADDLING babies - pacifiers and oral sucrose 25% half cc per kilogram of weight.

Category

Treatment - Drugs

2

Description

Intervention group 2: Ketamine 2mg/kg nasally is given to the patient thirty minutes before each examination by the nurse. Before pouring the ketamine drugs, the noses are suctioned and cleaned by pouring a drop of normal saline, and the drops are poured 5 minutes later.

Category

Treatment - Drugs

3

Description

Intervention group 3: Fentanyl 2 µg/kg nasally is given to the patient thirty minutes before each examination by the nurse. Before pouring the ketamine drugs, the noses are suctioned and cleaned by pouring a drop of normal saline, and the drops are poured 5 minutes later.

Category

Treatment - Drugs

4

Description

Intervention group 4: Acetaminophen 2 drops/kg orally is given to the patient thirty minutes before each examination by the nurse. Before pouring the ketamine drugs, the noses are suctioned and cleaned by pouring a drop of normal saline, and the drops are poured 5 minutes later.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiah Medical Educational and Therapeutic Center
Tehran

Full name of responsible person

Hamed razi

Street address

Mahdiah Hospital., Shahid Rajabnia Street., Shishagar Alley., Fadaian Islam Street., Shush Street., Tehran., Iran

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mahdiah_hospital@sbmu.ac.ir

Web page address

<https://mmc.sbmu.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice President of Research and Technology of Shahid Beheshti University of Medical Sciences.

Street address

Mahdiah Hospital., Shahid Rajabnia Street., Shishagar Alley., Fadaian Islam Street., Shush Street., Tehran., Iran

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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

Shahid Beheshti 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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hamed Razi

Position

Pediatric resident.

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Web page address<https://mmc.sbm.ac.ir/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Khoshnoud Shariati

Position

Assistant Professor of Neonatal and Perinatal Medicine.

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Assistant Professor of Neonatal Perinatal Medicine

Latest degree

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Other areas of specialty/work

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Web page address<https://mmc.sbm.ac.ir/>**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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only a part of the data, such as the information related to the main result or the like, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

It will be available only for researchers working in academic and scientific institutions after the official approval of the supervisor and main supervisor, and

other personal analyzes are not allowed.

From where data/document is obtainable

Mrs. Dr. Maryam Khoshnood Shariati Mahdiah Hospital
Tehran

What processes are involved for a request to access data/document

Visiting in person or calling Dr. Maryam Khoshnoud Shariati at Mahdiah Hospital in Tehran and registering a legal request at the Vice-Chancellor of Education at Mahdiah Hospital.

Comments