

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Effect of multisensory stimulation on pain of screening eye examination for retinopathy of prematurity in preterm neonates

Protocol summary

Summary

The purpose of the study is to examine the effect of multisensory stimulation on the pain caused by eye examination in an attempt to administer screening examinations for retinopathy of prematurity. In this randomized clinical trial, 80 preterm infants with a gestational age of 32 weeks or less based on baby's records, and infants who weigh less than 1500 gr at birth, or infants who weigh 1500 to 2000 gr and suffer from a severe systematic disease and age 4 weeks, were selected by an available sampling, and randomly divided into two groups; intervention and control. In the intervention group, a multisensory stimulation program runs. For tactile stimulation, baby's face, upper and lower limbs will be gently caressed by her mother. For visual stimulation, mother takes a close look at baby's face and attempts to make eye contact with her. For auditory stimulation, mother gently and continuously talks to her baby. For olfactory stimulation, the smell of vanilla will be used; which runs 15 minutes before examination starts and lasts until the examination starts. For gustatory stimulation, 33% glucose was used 2 minutes before examination starts. The control group received ordinary care in the ward. PIPP was used for pain assessment tool, the pain was examined in eight stages before intervention, before examination starts, during first eye and second eye examination, and in 4 30-second stages immediately after the end of eye examination.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014100119359N1**

Registration date: **2015-01-02, 1393/10/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-02, 1393/10/12

Registrant information

Name

Hossein Zeraati

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2014-07-05, 1393/04/14

Expected recruitment end date

2014-09-06, 1393/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of multisensory stimulation on pain of screening eye examination for retinopathy of prematurity in preterm neonates

Public title

Effect of multisensory stimulation on pain of eye examination in preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: preterm infants with a gestational age of 32 weeks or less based on baby's records, and infants who weigh less than 1500 gr at birth, or infants who weigh 1500 to 2000 gr and suffer from a severe systematic disease and age 4 weeks, in the presence of her mother. Baby is kept in a quiet and alert situation, her 5-minute Apgar score should not less than 6, and she has not taken any hypnotic drug within last 24 hours.

Exclusion criteria: during examination, baby seems to be in need of CPR, and she exhibits apnea symptoms.

Age

From **20 days** old to **1 month** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Vice Chancellor for Research, Building Qureshi, Daneshgah Street, Doctora Crossroads, Mashhad

City

Mashhad

Postal code

Approval date

2014-07-05, 1393/04/14

Ethics committee reference number

research/930010/1/1030

Health conditions studied

1

Description of health condition studied

preterm infant

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Pain score

Timepoint

Before intervention, before the eye examination, during the first eye examination, during the second eye examination, 4 stage 30 seconds after the eye examination

Method of measurement

Premature Infant Pain Profile tool

2

Description

Heart rate

Timepoint

Before intervention, before the eye examination, during the first eye examination, during the second eye examination, 4 stage 30 seconds after the eye examination

Method of measurement

Pulse oximetry

3

Description

Oxygen saturation

Timepoint

Before intervention, before the eye examination, during the first eye examination, during the second eye examination, 4 stage 30 seconds after the eye examination

Method of measurement

Pulse oximetry

4

Description

Behavioral condition

Timepoint

Before intervention, before the eye examination, during the first eye examination, during the second eye examination, 4 stage 30 seconds after the eye examination

Method of measurement

premature infant pain profile tool

5

Description

Facial expression

Timepoint

Before intervention, before the eye examination, during the first eye examination, during the second eye examination, 4 stage 30 seconds after the eye examination

Method of measurement

premature infant pain profile tool

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, multisensory stimulation program is implemented. For tactile stimulation, face, upper and lower limbs of infant will be stroking by the mother as a gentle. For visual stimulation, the baby's mother look closely and try to make eye contact with infant. For auditory stimulation, the baby's mother speaks slowly and continuously sustained with infant. For smell stimulation, vanilla will be used. This stimulation is applied 15 minutes before the start of the examination to start of examination. To stimulate the taste, the glucose of 33% was used 2 minutes before the examination

Category

Other

2

Description

The control group received usual care involves placing the baby in a relaxed environment before the examination.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-al-Anbia Hospital

Full name of responsible person

Hamidreza Behnam Vashani

Street address

Gharani boulevard, Mashhad.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Doctor Mohsen Tafaghodi

Street address

Vice Chancellor for Research, Building Qureshi, Daneshgah Street, Doctora Crossroads, Mashhad , Iran

City

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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

Vice Chancellor for Research, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Hossein Zeraati

Position

Master of Sciences in Neonatal Intensive Care Nursing

Other areas of specialty/work

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Full name of responsible person

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Position

Master of student in Neonatal Intensive Care Nursing

Other areas of specialty/work**Street address**

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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