

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Investigating the effect of multisensory stimulation and breast milk on intensity of pain In premature infants during examination for retinopathy screening

Protocol summary

Study aim

Investigating the effect of multisensory stimulation and breast milk on intensity of pain In premature infants during examination for retinopathy of prematurity

Design

A clinical trial with a control group and two intervention groups, including multi-sensory stimuli group and breast milk group, randomized, blinded

Settings and conduct

This randomized, single-blind randomized clinical trial will evaluate non-pharmacological interventions on neonatal pain severity during premature retinopathy examination in the NICU ward of Shahid Sadoughi Hospital in Yazd, with three groups, one control group and two intervention groups, including multi-sensory stimulation and breast milk.

Participants/Inclusion and exclusion criteria

Premature neonates born with a fetal age of 32 weeks and 6 days or less, or weighing 1,500 grams or less, or babies weighing between 1500 and 2000 grams with a course of unstable clinical conditions, admitted to Level 3 Neonatal Intensive Care Unit, who require retinopathy examination.

Intervention groups

The first group, the intervention group of multi-sensory stimuli, are included visual, taste, tactile, auditory and olfactory sensations in the neonate prior to examination. The second group, the breast milk Intervention group, will receive two cc of breast milk with a syringe , prior to examination . The third group, the control group, no intervention for the infant are taken.

Main outcome variables

Severity of pain, arterial oxygen saturation, heart rate, behavioral changes, facial changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180310039023N1**

Registration date: **2020-01-08, 1398/10/18**

Registration timing: **retrospective**

Last update: **2020-01-08, 1398/10/18**

Update count: **0**

Registration date

2020-01-08, 1398/10/18

Registrant information

Name

Kobra Mobashery zade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3263 2518

Email address

k.mobasheri@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-06-24, 1397/04/03

Actual recruitment end date

2019-01-09, 1397/10/19

Trial completion date

2019-01-09, 1397/10/19

Scientific title

Investigating the effect of multisensory stimulation and breast milk on intensity of pain In premature infants during examination for retinopathy screening

Public title

Investigating the effect of multisensory stimulation and breast milk on intensity of pain In premature infants in examination retinopathy

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Premature neonates born with a fetal age of 32 weeks and 6 days or less, or weighing 1,500 grams or less, or babies weighing between 1500 and 2000 grams, accompanied by a period of unstable clinical conditions that lasted 4 weeks after birth The baby is checked for the first time The baby is fed one hour before the examination and no longer fed The baby looks calm and alert. Parents' written and informed consent to study agreement of the doctor who do examine

Exclusion criteria:

The baby has a history of surgery and cardiopulmonary resuscitation, and lung hemorrhage Apgar 5 minutes less than 6 Painkillers have been prescribed for the baby for the past 24 hours The baby needs to have a positive pressure and tracheal tube ventilation The baby has abnormalities and problems with the nervous system, heart and respiratory system Babies who should not be fed(n.p.o)

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible infants are selected by Purpose-based sampling, and then assigned to one of three study groups by drawing method. The person who is unaware of the study will pick up one of the three numbers 1, 2 and 3 from the envelope

Blinding (investigator's opinion)

Single blinded

Blinding description

For the purpose of a single-blind study, individuals who are tasked with recording heart rate, oxygen saturation, and changes in face and behavior are blinded to the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

National Ethics Committee for Biomedical Research

Street address

Shahid Sadughi

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2018-05-16, 1397/02/26

Ethics committee reference number

IR.SSU.REC.1397.018

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

Pain Of Examination For Retinopathy

ICD-10 code

H35.1

ICD-10 code description

Retinopathy of prematurity

Primary outcomes**1****Description**

Intensity Of Pain

Timepoint

During Eye Examination For Retinopathy

Method of measurement

PIPP Tool

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group, after stabilization of infant's condition,the intervention including a multi sensory stimulation program (visual, taste, tactile, and smell stimulation)will be performed. At first, the infant is

placed at supine position, and the hands and legs are bent as the fetal position, so that the infant could move freely. For tactile stimulation, face, upper and lower limbs of infant is gently touched by the mother. The intervention is performed from 15 minutes before the beginning examination until the time of examination. For visual stimulation, the infant's mother will be asked to look at her baby from near and try for eye communication in order to attract the infant's attention. The intervention is performed from 15 minutes before the beginning examination until the time of examination. For hearing stimulation, the infant's mother will be asked to speak with her baby gently and continuously. The intervention is performed from 15 minutes before the beginning of examination until the time of examination. Lavender essential oil 2% is used for smell stimulation. The researcher stains a piece of sterile gauze with 5 drops of it and clamps into the infant dress. The intervention will be performed from 15 minutes before the beginning of examination until the time of examination. 1 ml of 33% glucose solution will be used for taste stimulation. Glucose solution will be drawn into a syringe by the researcher. The syringe mouth without needle will be placed into the infant's mouth and the solution will be injected into the infant's mouth with gentle movements along with infant's sucking for 30 seconds. This intervention starts 2 minutes before the examination. The mother will be instructed by the researcher before the intervention is performed. The procedure will be followed in a coordinated and similar manner, so that all mothers will do the same.

Category

Other

2

Description

Intervention group (breast milk): 2 ml of breast milk is drawn by the researcher into the syringe in 2 minutes before examination and poured into the baby's mouth gently for 30 seconds.

Category

Other

3

Description

Control group: The control group will receive no intervention, and routine care, including incubation and Nidcap care (neonatal individualized developmental care assessment plan), will be performed by mothers and staff on a regular and unplanned basis.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid sadughi hospital

Full name of responsible person

Dr Soleimani

Street address

Shahid ghandi Blvd, Ebn sina Blvd

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Sadoghi-hospital@ssu.ac.ir

Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Mirjalily

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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

Yazd University of Medical Sciences

Proportion provided by this source

1

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

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

Yazd University of Medical Sciences

Full name of responsible person

Khadije Dehghani

Position

Instructor and faculty member of Shahid Sadoughi

Faculty of Nursing and Midwifery, Yazd

Latest degree

Master

Other areas of specialty/work

Nursery

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Master student

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Other areas of specialty/work

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Full name of responsible person

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Fax**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