

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Study of the effect of Newborn Individualized Developmental Care and Assessment Program (NIDCAP) on pain caused by eye examination of screening for retinopathy of prematurity.

Protocol summary

Study aim

Determination of the effect of Newborn Individualized Developmental Care and Assessment Program (NIDCAP) on pain caused by eye examination of screening for retinopathy of prematurity.

Design

A randomized, single blinded, controlled clinical trial with a parallel group design of 60 newborn infant with gestational age less than 34 weeks or birth weight less than 2000 grams

Settings and conduct

Infants in the intervention group at Umm al-Benin Hospital in Mashhad and the control group at Khatam Hospital in Mashhad were studied. The examination of the intervention group (including the insertion of ophthalmology speculum and taking pictures by RetCam) is performed by a nurse. The pain of the examination is measured by the PIPP tool. Filming and evaluation of the following criteria for behavioral status and facial expression of PIPP pain tool was done by one person (supervisor) after viewing the films.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Newborn infant with gestational age less than 34 weeks or birth weight less than 2000 g which four weeks have passed since their birth. 2-Infant's mothers are present 3-Their parents are satisfied to participate in this research 4-At least one hour has passed from infant's feeding 5-Infants must be calm and alert 6-Infants take no sedatives in past 24 hours
Exclusion criteria: 1-Infants which need ventilator during examination 2-Infants which had asphyxia during examination

Intervention groups

Intervention group: Infants undergo NIDCAP actions from one hour before the examination until one hour after the examination. Control group: Infants of the control group are under common actions which are pouring anesthetic

drops into their eyes and then eye examination by RetCam to determine their pain score based on PIPP tool.

Main outcome variables

The heart rate and oxygen saturation of infants are measured in both groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180114038361N1**

Registration date: **2018-06-18, 1397/03/28**

Registration timing: **prospective**

Last update: **2018-06-18, 1397/03/28**

Update count: **0**

Registration date

2018-06-18, 1397/03/28

Registrant information

Name

Naimeh Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3823 4658

Email address

abbasin941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Newborn Individualized Developmental Care and Assessment Program (NIDCAP) on pain caused by eye examination of screening for retinopathy of prematurity.

Public title

The effect NIDCAP on pain caused by eye examination of screening for ROP

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Newborn infant with gestational age less than 34 weeks or birth weight less than 2000 g which four weeks have passed since their birth. Infant's mothers are present Their parents are satisfied to participate in this research At least one hour has passed from infant's feeding Infants must be calm and alert Infants must have no surgical history Infants must have no major congenital disorders like congenital heart or central nervous system disorders Infants take no sedatives in past 24 hours

Exclusion criteria:

Infants which need ventilator during examination Infants which had asphyxia during examination

Age

To 1 month old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

A blinded person (supervisor) will watch the videos and will set score of the PIPP tool

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

Fakouri Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2017-11-12, 1396/08/21

Ethics committee reference number

IR.MUMS.REC.1396.293

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

Retinopathy of Prematurity

ICD-10 code

H35.1

ICD-10 code description

Retinopathy of prematurity

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

Pain caused by eye exam of retinopathy of prematurity

Timepoint

Before, during and after eye exam

Method of measurement

using premature infant pain profile tool

Secondary outcomes

empty

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

Intervention group: Newborn Individualized Developmental Care and Assessment Program (NIDCAP)

Category

Behavior

2**Description**

Control group: Infants of the control group are under common actions which are pouring anesthetic drops into

their eyes and then eye examination by RetCam digital imaging system to determine their pain score based on PIPP tool.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommolbanin Hospital

Full name of responsible person

Naimeh Abbasi

Street address

Ommolbanin Hospital, Bahjat 16 Ave., Ayatollah Bahjat Street, Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3223 1061

Email

abbasin941@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94)

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3882 3255

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

Monir Ramezani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Doctora Junction, Eibn-sina st.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3841 3007

Email

ramezanim@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Monir Ramezani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Doctora Junction, Eibn-sina st.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3859 1511

Email

ramezanim@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Naimeh Abbasi

Position

Master Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, Doctora Junction,
Eibn-sina st.

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3859 1511

Email

abbasin941@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no need to add this types of data to published information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Master thesis and corresponding articles

When the data will become available and for how long

2018-2019

To whom data/document is available

Professors and students

Under which criteria data/document could be used

Researchers with related interest

From where data/document is obtainable

Faculty of nursing, Mashhad university of medical science

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

Contact to corresponding researchers of the thesis

Comments