

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The Effect of Eye shields and Earmuffs on the pain of Orogastric Tube (OGT) in premature infants in Neonatal Intensive Care Unit (NICU)

Protocol summary

Study aim

The effect of eye shields and earmuffs on the pain of Orogastric Tube in premature infants in Neonatal Intensive care Unit

Design

Two arm parallel group randomized trial, random allocation blocking sampling, Sample size is 110 for each group is 55 neonate

Settings and conduct

This research perform on 110 preterm infants between 36-28 weeks of gestation who are admitted in the NICU of Arash hospital.

Participants/Inclusion and exclusion criteria

inclusion: birth weight less than 2500 grams, Lack of mechanical ventilation exclusion: Congenital anomalies, or Genetic disorders

Intervention groups

Intervention group: The researcher uses earmuffs 4 hours before and during OGT treatment and eye shields are used 2 hours before OGT in intervention group. Then, the pain is measured for 30 seconds with Premature Infants Pain Profile 15 seconds before, during and after intervention. Control group: they receive routine care only.

Main outcome variables

The pain of Orogastric Tube in preterm infants will be examined by premature Infants pain Profile scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101113005163N7**

Registration date: **2018-10-02, 1397/07/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-02, 1397/07/10**

Update count: **0**

Registration date

2018-10-02, 1397/07/10

Registrant information

Name

Akram sadat Sadat hoseini

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Eye shields and Earmuffs on the pain of Orogastric Tube (OGT) in premature infants in Neonatal Intensive Care Unit (NICU)

Public title

The Effect of Eye shields and Earmuffs on the pain of OGT in premature infants in NICU

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The intrauterine age of the baby at birth on the basis of ultrasound in the first trimester of pregnancy and LMP between 28 weeks and 0 days to 36 weeks and 6 days Birth weight less than 2500 grams Healthy and vision-conscious babies

Exclusion criteria:

Any change in the condition of the baby during study days that results in receiving respiratory protection (attached to the ventylator) or receiving sedation or anticonvulsant Emergency delivery of oral and gastroduodenal tubes Congenital anomalies, or Genetic disorders Mechanical ventilation Consumption of effective drugs on the physiologic and therapeutic setting, such as anticonvulsants, sedation and opiate, at least 24 hours past Performing painful procedures before the intervention Infants who have had at least 24 hours of phototherapy treatment Infants born of mothers who do not have a history of drug use during pregnancy

Age

From **3 days** old to **50 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Neonates are selected in an accessible manner, and random allocation will be done in two intervention and control groups based on the blocking method. Random blocking is a randomized method that ensures that at each point of the research, roughly equal numbers of participants are assigned to all groups. The first step in determining the newborns in the intervention and control group is the formation of four blocks of intervention group (A) and control group (B).

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 Tehran University of Medical Sciences

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Nosrat St., Tohid Square

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Tehran

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1419733171

Approval date

2018-06-11, 1397/03/21

Ethics committee reference number

IR.TUMS.FNM.REC.1397.009

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

neonatal pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

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

Pain

Timepoint

Baseline which lasting 15 seconds before Intervention / During Intervention/30 seconds after the end of Intervention

Method of measurement

Premature Infants Pain Profile (PIPP) Scale

Secondary outcomes

empty

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

Intervention group: The researcher uses earmuffs (4 hours before and during inserting orogastric tube) and Eyeshield (2 hours before OGT) in this group. In order to compare pain in the normal state of the infant for 15 seconds in resting condition before performing OGT, during and after the completion of the work, pain measurement with Premature Infants Pain Profile is performed for 30 seconds. A camera captures facial manifestations and facial movements, and simultaneously captures another camera from the baby's pulse oximeter . The films are reviewed by the researcher and carefully studied in terms of changes in physiological and behavioral criteria, and the data will be entered and scaled according to PIPP tool criteria

Category

Other

2

Description

Control group: Newborn in the control group receive routine care. The pain is measured using the Premature Infants Pain Profile scale.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Akram sadat Sadat hoseini

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162 Allay, Shahid Baghdarnia st, After Shahid Bagheri Highway, Resalat Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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Six Floor, Research& Technology,Central Organization, Ghods st. ,Farmer Blvd, 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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Akrasadat Sadat Hoseini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Province

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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 program for Publishing participants data file.

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