

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the Effect of Vibration on Heel Lance Pain Control in Premature Infant Admitted to Neonatal Intensive Care Unit(NICU) Department Ali Ibn Abi Talib in Zahedan in 1398

Protocol summary

Study aim

Evaluation of the Effect of Vibration on Heel Lance Pain Control in Premature Infant Admitted to Neonatal Intensive Care Unit Department Ali Ibn Abi Talib in Zahedan in 1398

Design

Samples are assigned randomly (lottery) blocks to two groups of therapeutic vibration and control group, each block size being equal. Clinical trial, a randomized blinded.

Settings and conduct

The methodology will be to select from among the infants with the criteria and criteria for entry into the study, based on input criteria from the target population, namely preterm infants with a fetal age of 30 to 36 weeks and a weight greater than 1500 grams in Neonatal Intensive Care Unit of Ali ibn Abi Talib hospital is located in Zahedan and will be assigned to two groups of vibration (group A) and control (group B). For blinding In this study, sampling will be done by nurse and interventions by the researcher. The sampler is also aware that the sample is either a control group or an intervention. All interventions will be captured by the video camera.

Participants/Inclusion and exclusion criteria

All preterm infants 30 to 36 weeks and no congenital anomalies, respiratory distress and whose parents have completed consent form.

Intervention groups

Group A, therapeutic vibration. Group B, control and no intervention.

Main outcome variables

Pain: The score that the subject received after the end of the intervention by the pain measurement instrument used in preterm infants NIPS.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190530043765N1**

Registration date: **2019-06-09, 1398/03/19**

Registration timing: **prospective**

Last update: **2019-06-09, 1398/03/19**

Update count: **0**

Registration date

2019-06-09, 1398/03/19

Registrant information

Name

Yasin Ghodsi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 7573

Email address

yasin.ghodsi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Vibration on Heel Lance Pain Control in Premature Infant Admitted to Neonatal Intensive Care Unit(NICU) Department Ali Ibn Abi Talib in Zahedan in 1398

Public title

Evaluation of the Effect of Vibration on Heel Lance Pain Control in Premature Infant Admitted to Neonatal Intensive Care Unit(NICU) Department Ali Ibn Abi Talib in Zahedan in 1398

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pre-term infants with gestational age 30 to 36 weeks, weighing more than 1500 grams have. Their vital signs are within the normal range. Do not have severe respiratory distress. No congenital or anomalous defects. Their parents completed the consent form for participation in the research. Mother does not have drug addiction during pregnancy.

Exclusion criteria:

Intubated newborn during the study. Intubated the baby. Failure in the first time of blood sampling.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible babies will be selected in 1398 according to the entry criteria from the NICU section of the Ali ibn Abi Talib hospital in Zahedan. Samples are assigned randomly (lottery) blocks to two groups of vibration and control group, the size of all blocks is equal. In this method, the number of qualified preterm infants in both groups will be equally chosen.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, sampling will be done by nurse and interventions by the researcher. The sampler is also aware that the sample is either a control group or an intervention. All the interventions will be recorded by video camera. First, the staff of the department to scan and complete the form of the NIPS questionnaire, the film will be reviewed and then the researcher will review the accuracy of the questionnaire and final score will be given.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Zahedan University of Medical Sciences

Street address

Dr. Hassabi Square, Janat Blvd, Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Approval date

2019-05-26, 1398/03/05

Ethics committee reference number

IR.ZAUMS.REC.1398.094

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

The effect of vibration on pain relief from heel lance.

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

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

Pain: The score that the subject will take after the end of the intervention by the pain measurement instrument used in the preterm infants NIPS, and has a score of 0 to 7.

Timepoint

Measuring pain during heel lance with and without vibration.

Method of measurement

By the pain measurement tool used in preterm infants: Neonatal Infant Pain Scale

Secondary outcomes**1****Description**

Instrumentation of pain in term and preterm newborns before, during and after painful interventions such as blood sampling, venipuncture, vaccination and heel lance.

Timepoint

After sampling, the recorded video will be reviewed and rated.

Method of measurement

1.Cry, 2.Facial expression, 3.Breathing pattern, 4.Arms, 5.Legs, 6.State of Arousal.

Intervention groups

1

Description

Intervention group: Vibration during heel lance is performed on preterm infants who have criteria for entering the study. Then, pain measurement tools are completed in preterm infants and their pain score is measured.

Category

Treatment - Devices

2

Description

Control group: In this group, the blood from the heel without any intervention to be performed. The instrument for measuring pain in the preterm infants is completed and their pain score will be measured and then there will be a comparison between the pain score of the intervention group and the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali al-Ibn Abi Talib hospital in Zahedan

Full name of responsible person

Fereshteh Ghaljaei

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Zahedan, Dr. Hassabi Square, Jannat Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

NoorMohamad Bakhshani

Street address

Dr Hasabie Square, Persian Gulf Blvd, Pardis Office Complex, Zahedan University of Medical Sciences and Health Services

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Fereshteh Ghaljaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Mashahir square, Faculty of Nursing and Midwifery, Zahedan

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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

The main outcomes of the participants are public.

When the data will become available and for how long

6 months after the results.

To whom data/document is available

The researchers in academic and scientific institutions.

Under which criteria data/document could be used

The statistical result.

From where data/document is obtainable

Faculty of Nursing and Midwifery, Zahedan Telephone: 05433442481 Postcode: 9816913396 Address: Mashahir Square, Nursing and Midwifery Faculty, Zahedan

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

Contact the Nursing Faculty Library section.

Comments

does not have.