

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of vibration on pain Intensity of Heel-Blood Sampling in Neonates

Protocol summary

Study aim

Determination of the effect of vibration on pain intensity during heel blood sampling in neonates

Design

The study will be a clinical trial with a parallel control group without blinding. In this study, 94 infants will be selected by sequential method and randomly divided into control and intervention groups with 4 blocks sampling

Settings and conduct

The research setting will be the neonatal intensive care unit of Rasoul Akrami and intervention will be performed on the third day of hospitalization during screening tests

Participants/Inclusion and exclusion criteria

Neonates with a gestational age of 47-37 weeks, weighing between 2500 and 4000 g without heart, respiratory and neurological problems and without physical and chromosomal abnormalities were included in this study.

Intervention groups

1- Assessment of pain before intervention in experimental and control groups. 1- produce vibration by placing mechanical vibrator, approximately 30 seconds before the heel stick, the vibrator will be applied over the mid/lateral calf, just below the knee for 30-second in intervention group. 3- Re- assessment pain during heel blood sampling and 2 minutes after that in experimental and control groups.

Main outcome variables

Reduce pain during blood sampling by lancet the baby's foot

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160119026104N10**

Registration date: **2020-01-27, 1398/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-27, 1398/11/07**

Update count: **0**

Registration date

2020-01-27, 1398/11/07

Registrant information

Name

Mahnaz Shoghi

Name of organization / entity

Iran university of medical sciences

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Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vibration on pain Intensity of Heel-Blood Sampling in Neonates

Public title

Effect of vibration on pain Intensity

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Birth weight between 2500 to 4000 g No analgesics or

sedatives or anticonvulsants during the 12 hours prior to blood sampling No experience of painful procedure 24 hours before the intervention

Exclusion criteria:

Heart, respiratory and neurologic problems or any chromosomal and anatomical abnormalities

Age

From **256 days** old to **294 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **47**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation blocks of two groups with four blocks

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 Iran University of Medical Sciences

Street address

Tehran, Valiasr Ave., higher than Vanak Square, Rashidiassemi Avenue, Iran Nursing Midwifery Faculty

City

Tehran

Province

Tehran

Postal code

1996713883

Approval date

2018-09-28, 1397/07/06

Ethics committee reference number

IR.IUMS.REC.1397.510

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Pain measurement before intervention, Pain measurement during heel blood sampling, Pain measurement 2 minutes after heel blood sampling

Method of measurement

Premature Infant Pain Profile (PIPP)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Use a mini vibrator(Norco MiniVibrator North Coast Medical Inc,NC70209, Gilroy, California) operates at 92 Hz and an amplitude of 0.6 mm) . to produce Vibration by placing the vibrator for 5 seconds before taking blood sampling from the baby's heel, in place of over the mid/lateral calf, just below the knee in accordance with the sural dermatome)

Category

Other

2

Description

Control group: Assessment of pain before, during and 2 minutes after taking blood sampling from infant's heel.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Ms. Azam Abbasi

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Sattar Khan Street. Niyayesh Street. Rasoul-e-Akram

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Iran 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

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Associate professor
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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

After Data coding in order to keep the confidentiality of the participants in the research.

When the data will become available and for how long

The end of sampling till six months after article publishing.

To whom data/document is available

Ethical, Reviewer and Editorial committees, Researchers.

Under which criteria data/document could be used

Systematic review and meta-analysis or secondary analysis citation

From where data/document is obtainable

Mahnaz Shoghi, Email: shoghi.m@iums.ac.ir

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

After sending a request to academic email, we will send our data files up to one week.

Comments