

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Assessing of impact the auditory familiar stimulation on physiological responses caused by painful stimuli in newborns hospitalized in NICU

Protocol summary

Summary

The purpose of this study was to Assess of impact the auditory familiar stimulation on physiological responses caused by painful stimuli in newborns hospitalized in NICU. Inclusion criteria: Infants hospitalized in neonatal intensive care units in selected hospitals in Tehran; when measuring pain or at least 3 hours before it, Sedatives have not received; The lack of Underlying disease and extensive surgery (e.g., abdominal surgery, etc.) that is causing pain; The lack of crippling diseases and anatomical defects members (hands and feet); No hearing impaired; At least 36 weeks gestational age; Requiring Blood samples is. Exclusion criteria: During the study, the infant is in trouble, as it is connected to the ventilator; when sampling is not done once the needles into the skin; when sedatives or tranquilizers should be used for infants during Blood samples. The population included all infants admitted to the intensive care unit of a hospital, sampling is simple random sampling. There are 60 samples and is performed by both sexes. From 10 minutes before to 10 minutes after taking blood samples mother's voice is played And physiological responses before, during and 10 minutes after blood samples are document and pain at the time of entry and one minute after needle insertion is measured Using NIPS scale, Then effects on physiological responses to pain compared with a control group of infants who are not playing mother's voice.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011416225N1**

Registration date: **2014-08-03, 1393/05/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-03, 1393/05/12

Registrant information

Name

Elham Azarmnejad

Name of organization / entity

Baghiatollah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00982122286057-22289941

Email address

azarm.elham@yahoo.com

Recruitment status

Recruitment complete

Funding source

Baghiatollah University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-08-26, 1393/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing of impact the auditory familiar stimulation on physiological responses caused by painful stimuli in newborns hospitalized in NICU

Public title

Familiar auditory stimuli on physiological responses induced by painful stimulation in infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Infants hospitalized in neonatal intensive care units in selected hospitals in Tehran; when measuring pain or at least 3 hours before it, Sedatives have not received; The lack of Underlying disease and extensive surgery (e.g., abdominal surgery, etc.) that is causing pain; The lack of crippling diseases and anatomical defects members (hands and feet); No hearing impaired; Must have at least 36 weeks gestational age; Requiring Blood samples is. Exclusion criteria: During the study, the infant is in trouble, as it is connected to the ventilator; when sampling is not done once the needles into the skin; when sedatives or tranquilizers should be used for infants during Blood samples

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baghiatollah University of Medical Sciences

Street address

Mollasadra street

City

Tehran

Postal code

Approval date

2014-05-25, 1393/03/04

Ethics committee reference number

5291/3/340/س

Health conditions studied

1

Description of health condition studied

Understand the relationship between auditory stimulation on physiological responses induced by painful stimulation in infants hospitalized in intensive care

ICD-10 code

General sy

ICD-10 code description

Acute pain R52.0

Primary outcomes

1

Description

Physiological responses

Timepoint

Before the intervention, during intervention, post-intervention

Method of measurement

Using a pulse oximeter Mobile

Secondary outcomes

1

Description

Pain

Timepoint

Before the intervention, during intervention, post-intervention

Method of measurement

NIPS pain scale

Intervention groups

1

Description

In the test group, the mother's voice is played for 10 minutes before and 10 minutes after blood sampling continues. Mother's voice can be recorded using a software program, Cool Edit2000, and with two small speakers on either side of the Infant's head at a distance of 20 cm from the Infant's ear, placed in the incubator. The Voice being broadcast in about 50 to 60 dB is set.

Category

Other

2

Description

In the control group, no interventions are not just physiological variables (heart rate, respiratory rate, blood pressure, oxygen saturation, and pain) are measured.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiatollah Hospital

Full name of responsible person

Forough Sarhangy

Street address

Mollasadra street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baghiatollah University of Medical Sciences

Full name of responsible person

Dr. Rokhsari

Street address

Alley Borna-Sheikh Bahai Avenue South

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Baghiatollah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Baghiatollah University of Medical Sciences

Full name of responsible person

Elham Azarmnejad

Position

Master student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Position

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty