Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Assessing of impact the mother's heart rate on physiological responses caused by painful stimuli in newborns hospitalized in NICU

Protocol summary

Summary

The study was a randomized clinical trial on 60 term infants hospitalized in Baghiatollah Hospital in 2014. The newborns were randomly divided into intervention(n = 30) and control groups (n = 30). The infants of the intervention group received their mother's heartbeat 10 minutes before the bleeding was started up to 10 minutes after the bleeding was completed. Control group infants received blood samples without heartbeat. Pain intensity every 10 minutes in 3 steps: 10 minutes before the intervention (before playing the mother's heart sounds), during intervention, and 10 minutes after the intervention (immediately after the completion of the sound) with the Infant Pain Scale (NIPS) Neonatal Scale and Physiological variables were recorded by mobile pulsed oximetry device.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072916225N3**
Registration date: **2017-08-07, 1396/05/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-08-07, 1396/05/16

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 Hospital

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 mother's heart rate on physiological responses caused by painful stimuli in newborns hospitalized in NICU

Public title

The effect of mother's heart rate in hospitalized neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Infants hospitalized in neonatal intensive care units when measuring pain or at least 3 hours before it, Sedatives have not received; The lack of Underlying disease and extensive surgery ; The lack of crippling diseases and anatomical defects members ; No hearing impaired; Must have at least 36 weeks gestational age. 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

Age

To **1 day** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
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
Mother's heart beat relationship to physiological responses from painful stimuli in infants admitted to the intensive care unit
ICD-10 code
ICD-10 code description

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 heartbeat 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 Hospital
Full name of responsible person

Baghiatollah Hospital

Street address

Mollasadra street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Baghiatollah Hospital

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

Baqiatollah hospital

Full name of responsible person

Elham Azarmnejad

Position

Master of nursing

Other areas of specialty/work

Street address

Mollasadra street

City

Tehran

Postal code

Phone

+98 217736000600

Fax

Email

azarm.elham@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Baghiatollah Hospital

Full name of responsible person

Elham Azarmnejad

Position

Master of nursing

Other areas of specialty/work

Street address

Shahed alley, Kelagermahalle street

City

Jouybar

Postal code

4771966349

Phone

+98 11 4254 2397

Fax

Email

azarm.elham@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Baghiatollah Hospital

Full name of responsible person

azarm.elham@yahoo.com

Position

Master of nursing

Other areas of specialty/work

Street address

Shahed alley- Kelagermahale street

City

Jouybar

Postal code

Phone

+98 11 4254 2397

Fax

Email

azarm.elham@yahoo.com

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