Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of sound reduction management on preterm neonate’ stress in NICU

Protocol summary

Study aim
The aim of this study is to assess the effect of sound reduction management on preterm neonate’ stress in NICU.

Design
This study will done as a quasi experimental clinical trial with control & intervention group from same environment and sampling according to available samples with factorial groups & 90 samples and phase 3.

Settings and conduct
Current quasi experimental study will done in NICU1 of Therapeutic Complex of emam ALI in Alborz - Iran. Samples in intervention and control groups will choose from same ward.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Neonate without congenital abnormality on birth, gestational age 26-36 week and birth weight 1000-2500 gr.Neonate admit to NICU at birth, don't have mother with addiction, don’t take sedative during study and at least one hour before sampling, painful procedure wouldn’t carry out for them. If neonates become ill, die or send to another hospital or have a surgery during study they will excluded from study.

Intervention groups
In intervention group neonates after doing intervention of reducing sounds will assess for level of stress with measuring saliva cortisol. In control group neonates before doing intervention receive routine care of ward and sampling of saliva cortisol will done for them.

Main outcome variables
Level of preterm neonate' stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090405001788N20**
Registration date: **2018-11-19, 1397/08/28**
Registration timing: **retrospective**

Last update: **2018-11-19, 1397/08/28**
Update count: **0**

Registration date
2018-11-19, 1397/08/28

Registrant information

Name
Leili Borimnejad

Name of organization / entity
Iran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 6150 4212

Email address
borimnej@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-06, 1397/04/15

Expected recruitment end date
2018-10-23, 1397/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of sound reduction management on preterm neonate’ stress in NICU

Public title
Effect of sound reduction management on preterm neonate’ stress in NICU

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Neonate born with gestational age 26-36 week. Neonate with birth weight 1000-2500 gr. Neonate admit to NICU at birth. At least one hour before sampling painful procedure wouldn't carry out for infant.
Exclusion criteria:
Infant take sedative during study. Addicted mother Neonate with congenital abnormality on birth.
Age
From **2 days** old to **3 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
More than 1 sample in each individual
Number of samples in each individual: **3**
For each sample 3 times in 3 consecutive days saliva cortisol sample will take.
Randomization (investigator's opinion)
N/A
Randomization description
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 Seinces
Street address
Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2018-10-25, 1397/08/03
Ethics committee reference number
IR.IUMS.REC.1397.343

Health conditions studied

1

Description of health condition studied
Assess of level of preterm neonate' stress
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Preterm neonate' stress
Timepoint
second to third days of birth
Method of measurement
Measuring level of saliva cortisol of samples

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For assessing the effect of sound reduction management on preterm neonate' stress interventions for 3-4 weeks to reducing noise take place that it contain a combination of educational programs, reducing alarms of equipment and phone and doors sound, transfer neonates to incubator and teaching parents from time of admit about reducing noise. 2 weeks after intervention programs, sampling for saliva cortisol of preterm neonate in intervention group take place. Sampling for all infants 48-72 hours after birth and at 9-10 AM by sterile catheter, collecting in captive tube and will store in -20 temperature until analyzing. Samples will take for each neonate 3 times in 3 consecutive days. Samples for measuring cortisol will analysis by CLIA method. Sampling will do according to available samples and all neonates that admit to ward during study will assess. Due to the property of research community and difference of development level of neonates (gestational age 26-32, 32-36), A6 variable is base of planning study as Randomized block design.
Category
Behavior

2

Description
Control group: Samples in control group before doing interventions for reducing sound will take routine care and sampling will done for them like intervention group with same condition.
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Therapeutic - educational Complex of emam ALI

Full name of responsible person
DR. Mahdavi Ahmad

Street address
Azymiee forked road

City
Karaj

Province
Alborz

Postal code
3136735173

Phone
+98 26 3252 7575

Fax
+98 26 3254 7128

Email
EMAMALI@abzums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seid Kazem Malakouti

Street address
Hemmat Highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Phone
+98 21 86710

Email
research@iums.ac.ir

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
75

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
Iran University of Medical Sciences

Full name of responsible person
Dr. Leili Borimnejad

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Rashid Yassemi,Valiasr

City
Tehran

Province
Tehran

Postal code
1996713883

Phone
+98 21 8888 2886

Email
borimnejad.l@iums.ac.ir

Web page address
htpp://fnm.iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Leili Borimnejad

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Rashid Yassemi,Valiasr

City
Tehran

Province
Tehran

Postal code
1996713883

Phone
+98 21 8888 2886

Email
borimnejad.l@iums.ac.ir

Web page address
htpp://fnm.iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Leili Borimnejad

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
School of Nursing and Midwifery, Rashid Yassemi,Valiasr

City
Tehran

Province
Tehran

Postal code
1996713883

Phone
+98 21 8888 2886

Email
borimnejad.l@iums.ac.ir

Web page address
htpp://fnm.iums.ac.ir

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
Not applicable

Title and more details about the data/document
Data coding will done In order to keep confidentiality of the participants in the research.

When the data will become available and for how long
The end of sampling till six month after article publishing.

To whom data/document is available
Ethical , reviewer and editorial committees and other researchers.

Under which criteria data/document could be used
Systematic review and meta analysis or secondary analysis citation.

From where data/document is obtainable
Leili Borimnejad , borimnejad.l@iums.ac.ir

What processes are involved for a request to access data/document
After sending request by academic email, we will send them data files up to one week.

Comments