Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of maternal sound on neonatal vital signs in preterms admitted in NICU

Protocol summary

Summary

this is a semiexperimental study with repeated measurments for evaluation of taped maternal voice on physiologic responce in their neonates. The duration of study is three consequative days. The populatin are selected by inclusion and exclusion criteria (neonate who not receiving respiratory support , oxygen and cardiotonic drug).30 neonates admitted in shariati hospital NICU who at least are 2 days old ;in addition to routine care ,recieve their taped maternal sound 3 times per day for 3 days. the duration of intervention is 15 min in each times.at the first 5 min we collect basal data and then in second 5 min the sound of mother report and then at the last 5 min we continue monitoring of vital sign. The intensity of sound is below 50 decible.The collected data are Respiratory rate ,heart rate and o2 saturation .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111268199N1**
Registration date: **2012-03-08, 1390/12/18**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-03-08, 1390/12/18

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source
Tehran university of medical sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of maternal sound on neonatal vital signs in preterms admitted in NICU

Public title

Evaluation of maternal sound on neonatal physiologic response in preterms admitted in NICU

Purpose

Supportive

Inclusion/Exclusion criteria

inclusion criteria: gestetional age 32-34;post natal age more than 2 day of old;no congenital or neurologic abnormality;no asphyxia; exclusion criteria:history of maternal addiction;any need to respiratory support intraventricular hemorrhage more than grade 2;history of any cardiotonic agent or muscle relaxant usage for neonate; metabolic disease;any neonatal bacterial ,viral or fungal infection;paternal disagrrement to continue study

Age

From **1 year** old to **28 years** old

Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University Of Medical Sciences
Street address
Keshavarz Blv , Tehran
City
Tehran
Postal code
Approval date
2012-02-01, 1390/11/12
Ethics committee reference number
45152

Health conditions studied

1

Description of health condition studied
Evaluation of maternal sound on neonatal phsiologic responces in preterms admitted in NICU ward
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
respiratory rate
Timepoint
at the end of every 5 min of intervention
Method of measurement
respiratory rate measurment by researcher aid

2

Description
heart rate
Timepoint
at the end of every 5 min of int
Method of measurement
by cardiorespiratory manitor

3

Description
o2 saturation measurment
Timepoint
at the end of every 5 min of intervention
Method of measurement
by pulse oximetry

Secondary outcomes

1

Description
gestetional age
Timepoint
at birth time
Method of measurement
by demographic questienary

2

Description
post natal age
Timepoint
at the time of intervention
Method of measurement
by demographic questienary

3

Description
sex
Timepoint
at birth time
Method of measurement
by physical exam

4

Description
birth weight
Timepoint
at birth time
Method of measurement
by digital scale

Intervention groups

1

Description
recording maternal sound in 5 min for every intervention (3 intervention per day).Every neonate expose to

maternal sound 9 times during intervention
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Negar Sajjadian
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North Kargar, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University Of Medical Sciences
Full name of responsible person
Sponsor of tehran medical university
Street address
keshavarz Blv, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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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