

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

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

Protocol summary

Summary

this is a semiexperimental study with repeated measurements for evaluation of taped maternal voice on physiologic response in their neonates. The duration of study is three consecutive days. The population 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 ,receive 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

Name

Negar Sajjadian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2541

Email address

nsajadian@tums.ac.ir

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: gestational 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 disagreement 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 physiologic responses 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 measurement 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 questionary

2

Description

post natal age

Timepoint

at the time of intervention

Method of measurement

by demographic questionary

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
Street address
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

Contact

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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