

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of mother's voice on preterm neonates' physiological parameters and mothers' parental perception in the Neonatal Intensive Care Unit of Mehr Hospital, Malayer,2016.

Protocol summary

Summary

The main objective of the project: The effect of mother's voice on preterm neonates' physiological parameters and mothers' parental perception in the Neonatal Intensive Care Unit. Secondary objectives: Compare neonate's heart rate and oxygen saturation before, during and after the intervention. Compare mothers' parental perception before, during and after intervention. Inclusion criteria: Age at birth based on the result of history, ultrasound between 30-37 weeks; Is incubated; Not under mechanical ventilation; No intrauterine growth retardation; Intracerebral hemorrhage is not more than grade 2; Infant bed lowering therapy not conscious; Two days of infant hospitalization in the past; Baby's chromosomes or abnormalities, congenital anomalies haven't; The doctor is certified by reflex Moro infant hearing health advice; doesn't distress breathing; Not multiple. Mother: Drug addiction is not; history of smoking cigarettes during pregnancy is not; known any psychological illness resulting in hospitalization is not. Study population: mothers and preterm infant hospitalized in the neonatal intensive care unit. Sample: 36 neonates, 36 mothers. Intervention: speech mother with preterm neonates. Time: 10 minutes. Primary outcome: improve oxygen blood, respiratory rate, stability heart rate in neonate, increase mothers' parental perception.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016072729104N1**
Registration date: **2016-09-23, 1395/07/02**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-23, 1395/07/02

Registrant information

Name

Zahra Afshari

Name of organization / entity

Hamedan University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Hamedan University Of Medical Sciences

Expected recruitment start date

2016-08-27, 1395/06/06

Expected recruitment end date

2016-10-06, 1395/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of mother's voice on preterm neonates' physiological parameters and mothers' parental perception in the Neonatal Intensive Care Unit of Mehr Hospital, Malayer, 2016.

Public title

The effect of mother's voice on preterm neonates' vital

signs and mothers' parental perception in the Neonatal Intensive Care Unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age at birth based on the result Imp history, ultrasound between 30-37 weeks; Is incubated;Not under mechanical ventilation;No intrauterine growth retardation; Intra cerebral hemorrhage is not more than grade ; Infant not treated with drugs to reduce the level of conscious ;Two days past of infant's hospitalization Baby's chromosomes or abnormalities, congenital anomalies havenot;The doctor is certified infant's hearing health by reflex moro;neonate dosent respiratory distress ;Not multiple. Mother: Drug addiction is not ;history of smoking cigarettes during pregnancy is not;known any psychological illness resulting in hospitalization is not. exclusion criteria early discharge infant;any change in the status of infant was taken to'll need to get respiratory support; symptoms of hypoglycemia or hypocalcemia; the absence of a parent to continue project.

Age

From **2 days** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **36**

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

Hamedan Of university sciences

Street address

Hamedan, Opposit Mardom Park, Shahid Fahmide Avenue

City

Hamedan

Postal code

6517838698

Approval date

2016-05-15, 1395/02/26

Ethics committee reference number

IR.UMSHA.REC.1395.91

Health conditions studied

1

Description of health condition studied

PRETERM NEONATE

ICD-10 code

060-075

ICD-10 code description

Complications of labour and delivery

Primary outcomes

1

Description

HEART RATE

Timepoint

5 MINUTE BEFOR INTERVENTION 10 MINUTE DURING INTERVENTION 5MINUTE AFTER INTERVENTION

Method of measurement

HR MEASURE BY MONITORING DEVICI IN 1 MINUTE

2

Description

Respiratory rate

Timepoint

5 MINUTE BEFOR INTERVENTION 10 MINUTE DURING INTERVENTION 5MINUTE AFTER INTERVENTION

Method of measurement

COUNTING RESPIRATORY RATE IN1 MINUTE BY RESEARCHER

3

Description

SATURATION O2 PERCENT

Timepoint

5 MINUTE BEFOR INTERVENTION 10 MINUTE DURING INTERVENTION 5MINUTE AFTER INTERVENTION

Method of measurement

HR MEASURE BY MONITORING DEVICI IN 1 MINUTE

4

Description

mothers' parental perception

Timepoint

first day befor intervention and the end third day

Method of measurement

mothers' parental perception questionnaire

Secondary outcomes

1

Description

sever reactoin to acoustic stimulationby syptom cry ,screaming

Timepoint

in time intrvention: 10 minute

Method of measurement

by observing neonate

Intervention groups

1

Description

speach mother with preterm neonate10 minute in 3 days consecutive in intervention group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehr Hospital

Full name of responsible person

Zahra Afshari

Street address

Malayer Nabovat Avenu

City

Malayer

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center Shool Of NursingUniversity Hamedan

Full name of responsible person

Fateme Cheragi

Street address

Hamedan,Across Mardom Park. Shahid Fahmide Avenu

City

Hamedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research center Shool Of NursingUniversity Hamedan

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

Hamedan University Of Medical Sciences

Full name of responsible person

Zahra Ashari

Position

Student BA. Nurse

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty