Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 befor, during and after the intervention. Compar mothers' parental perception before ,during and after intervention Inclusion criteria: Age at birth based on the result lmp 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 beds lowering therapy not conscious ;Two days of infant hospitalization in the past; Baby's chromosomes or abnormalities, congenital anomalies havenot;The doctor is certified by reflex moro infant hearing health advice;doesnt 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 sampel:36 neonates,36 mothers intervention:speech mother with preterm neonates time:10minutes primary outcome:improve oxyjen blood,respiratory rate,stability heart rate in neonate,incease 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

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Recruitment status

Recruitment complete

Funding source

Hamedan Univresity 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 lmp 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 thirth 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
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Malayer

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research center Shool Of NursingUniversity Hamedan
Full name of responsible person
Fateme Cheragi
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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
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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