

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the effect of auditory and tactile stimulation on nutritional adequacy and physiological indicators of premature babies hospitalized in neonatal intensive care

Protocol summary

Study aim

Comparison of the effect of auditory and tactile stimulation on nutritional adequacy and physiological indicators of premature infants admitted

Design

It has a control group and two intervention groups, without blinding in a simple random manner on 90 newborns

Settings and conduct

It is performed in the neonatal intensive care unit of Ali Bin Abitalib Zahedan Hospital. Also, based on the nature of the intervention and its effect on other patients, all interventions are done individually.

Participants/Inclusion and exclusion criteria

The age of the baby is between 32 and 36 weeks of gestation, APCAR is between 8 and 10, the weight of the baby 1500 and 2500 grams, and among the exit criteria; seizures and discharge .

Intervention groups

two intervention groups (tactile and auditory stimulation) and a control group

Main outcome variables

Adequacy of nutrition, physiological indicators

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200918048750N2**

Registration date: **2023-08-08, 1402/05/17**

Registration timing: **prospective**

Last update: **2023-08-08, 1402/05/17**

Update count: **0**

Registration date

2023-08-08, 1402/05/17

Registrant information

Name

Mahnaz Ghaljeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3342 0641

Email address

ghaljeh.m@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-22, 1402/05/31

Expected recruitment end date

2024-08-21, 1403/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of auditory and tactile stimulation on nutritional adequacy and physiological indicators of premature babies hospitalized in neonatal intensive care

Public title

Comparison of the effect of auditory and tactile stimulation on nutritional adequacy and physiological indicators of premature infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Persistence of infant's physiological symptoms
No respiratory distress
Not using narcotic drugs and sedatives for the baby
Apgar score between 8-10
Completion of the consent form of the baby to participate in the research by the father or mother
Absence of congenital anomalies
Feeding babies with stored breast milk
Low birth weight babies weighing 1500 to 2500 grams

Exclusion criteria:

Seizure of the baby to be discharged
Death of a baby
Changes in the clinical condition of the baby, such as intubation of the baby
hemodynamic disorder during the study (heart rate more than 180 or less than 100 times per minute, breathing more than 60 or less than 30 times per minute, decrease in arterial blood oxygen saturation percentage less than 86%)

Age

From **4 days** old to **7 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done by available methods. All premature babies hospitalized in the neonatal intensive care unit of Ali Ibn Abi Talib Zahedan Hospital who meet the inclusion criteria will be included in the study. Then the selected babies are randomly divided into three groups: auditory stimulation, tactile stimulation and control group. In this way, first, envelopes containing the names of the groups will be prepared for the total number of studied samples and randomly arranged, and gradually, one of the cards will be assigned to them, which will determine the individual's group in the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Infants born at least 32 weeks are pre-terminated.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical

Sciences

Street address

Dr. Hasabi Square, Baluchistan Blvd, Zahedan
University of Medical Sciences

City

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Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2023-06-18, 1402/03/28

Ethics committee reference number

IR.ZAUMS.REC.1402.150

Health conditions studied

1

Description of health condition studied

Premature infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Nutritional adequacy: It is the amount of milk that the baby eats in the first ten minutes of feeding, which is calculated in milliliters per minute.

Timepoint

Since the babies hospitalized in the intensive care unit are fed every two hours according to the doctor's order, for the post-test at 8:00 am after changing the diaper, the amount of milk ordered by the doctor was poured into the syringe and injected through the syringe. The mouth was given to the baby by a peso-stimulator and the amount was recorded in cc/min. Again, after the intervention (auditory or tactile) at 10 o'clock, the prescribed amount of breast milk was poured into the syringe and given to the baby through the mouth by the researcher, and the amount of cc per minute was recorded. The intervention will be carried out once a day in the morning shift for 3 days (on the fourth, fifth and sixth days of hospitalization).

Method of measurement

The amount of milk that the baby eats in the first ten minutes of feeding, which is calculated in milliliters per minute.

2

Description

Physiological indicators (heart rate, breathing rate and blood oxygen saturation percentage) are measured by SAADAT brand monitoring whose probe is attached to the baby's right hand.

Timepoint

At 8 am before the intervention and at 10 am after the intervention, physiological indicators are measured

through monitoring.

Method of measurement

Physiological indicators (heart rate and breathing rate and blood oxygen saturation percentage) are recorded and measured by monitoring with SAADAT brand whose probe will be attached to the baby's right hand.

Secondary outcomes

empty

Intervention groups

1

Description

If the patient was placed in the auditory stimulation intervention group, the demographic questionnaire form was first filled by the researcher, before the intervention, an individual training session was held for the mother and baby for 30 to 45 minutes and the method of auditory stimulation was explained, which includes reading a lullaby in the mother's own dialect. At 8 o'clock in the morning, the amount of milk prescribed by the doctor is poured into the syringe (SUPA) and given to the baby through the mouth by the researcher, and the amount of cc per minute is recorded, as well as the physiological indicators (heart rate, breathing rate and blood oxygen saturation percentage) It is measured by monitoring with the SAADAT brand, whose probe is attached to the baby's right hand. In the next step, at 10 o'clock in the morning, the mother will be present at the baby's bedside, for three minutes, a lullaby for baby, immediately after the intervention of the milk amount. The order given by the doctor was poured into the syringe and given to the baby through the mouth by the researcher, and the amount of cc per minute is recorded and the physiological indicators are also measured.

Category

Behavior

2

Description

If the patient is included in the tactile stimulation intervention group, first the demographic questionnaire form will be completed by the researcher and an individual training session will be held for the mother of the baby for 30 to 45 minutes and how to perform the tactile stimulation that is taught to the mothers in such a way that first they must disinfect their hands with an antibacterial solution, after warming the hand under the warmer, place one hand in a cup shape around the baby's head above the eyebrow line and place the other hand on the lower abdomen around the baby's waist and hips. The hands should be placed gently on the baby's body and only the hand should be in contact with the baby and no pressure should be applied to the baby's body. At 8 o'clock in the morning, the amount of milk ordered by the doctor is poured into the syringe (SUPA) and is given to the baby through the mouth by the researcher, and the amount of cc per minute is recorded, the physiological indicators (heart rate and

breathing rate and percentage blood oxygen saturation is measured by monitoring with SAADAT brand, whose probe is attached to the baby's right hand. In the next step, the mother is present at the baby's bedside at 9:45 a.m., and she is asked to perform tactile stimulation for 15 minutes. Then, at 10 o'clock, the amount of milk ordered by the doctor is poured into the syringe, it is given to the baby through the mouth, and the amount of cc per minute is noted, and the physiological indicators are also measured.

Category

Behavior

3

Description

Control group: First, the demographic questionnaire form was completed by the researcher at 8 o'clock in the morning, after changing the diaper, the amount of milk ordered by the doctor was poured into the syringe and given to the baby through the mouth by the researcher, and the amount of cc per minute was noted. Physiological indicators are also measured. The infants of this group do not receive any intervention except for routine care according to the hospital's policy, again at 10 o'clock nutrition adequacy and physiological indicators are measured by the researcher.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences, Imam Ali Hospital

Full name of responsible person

Mahnaz Ghaljeh

Street address

Imam Ali Hospital, Dr. Hasabi Square, Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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public@zaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

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**

Zahedan University of Medical Sciences

Full name of responsible person

Mahnaz Ghaljeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available