

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of breast milk odor on respiratory distress and oxygen saturation of preterm infants in intensive care unit

Protocol summary

Study aim

The effect of breast milk odor on respiratory distress and oxygen saturation of preterm infants in neonatal intensive care unit

Design

The clinical trial with intervention, control and placebo groups with parallel groups, one-way blind, approved on 96 infants and performed through a table of random numbers and block method.

Settings and conduct

96 premature infants admitted to the neonatal intensive care unit are selected by easy sampling method and in case of access to Israel, inclusion criteria and no. , And control (each group of 32 people) is divided.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The infant should be in the first 24 hours after birth 2. Intrauterine age of at least 37 weeks at birth 3. Stored inside the incubator 4. Infant body temperature in the range of 2.37-36.36 degrees 5. RDS score should be between 5 and 8 6. Apgar fifth minute, seven and more 7. Mother does not use cigarettes, alcohol or drugs 8. No severe congenital anomalies and congenital infections 9. The baby is not under Early Cpap
Exclusion criteria: 1. Having a secondary infection 2. Seizures 3. Consecutive apneas 4. Grade 3 and 4 intraventricular hemorrhage based on third day ultrasound 5. Diagnosis or death of the infant before the intervention

Intervention groups

96 premature infants admitted to the neonatal intensive care unit are divided into 3 groups: breast milk odor, formula milk odor, and control (32 patients in each group).

Main outcome variables

respiratory distress; Oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210227050516N1**

Registration date: **2021-04-11, 1400/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-11, 1400/01/22**

Update count: **0**

Registration date

2021-04-11, 1400/01/22

Registrant information

Name

FATEMEH SHEIKHSHOAAEE

Name of organization / entity

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Iran (Islamic Republic of)

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+98 25 3288 0994

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-06, 1399/12/16

Expected recruitment end date

2021-06-06, 1400/03/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of breast milk odor on respiratory distress and oxygen saturation of preterm infants in intensive care unit

Public title

The effect of breast milk odor on respiratory distress and oxygen saturation of preterm infants in intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The baby should be in the first 24 hours after birth
Intrauterine age less than 37 weeks at birth
Stored inside the incubator
The baby's body temperature is in the range of 36.2 / 36.7 degrees Celsius
RDS score Between 5 and 8
Apgar score is five minutes, seven and more
Mother of cigarettes, alcohol or unused drugs
No severe congenital anomalies and congenital infections
The baby is not under Early Cpap

Exclusion criteria:

Having a secondary infection
Seizures
Consecutive apnea
Grade 3 and 4 intraventricular hemorrhage based on third day ultrasound
Registration or death of the infant before the intervention

Age

From **1 day** old to **5 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, first, individuals are entered into the study in an accessible manner based on inclusion and exclusion criteria, and then, using permutation blocks, they are divided into two groups: breast milk odor and formula milk odor (32 people in each group) and will be allocated. In this method, if we consider the odor group of breast milk as A, the odor group of formula as B, the 6 possible states will be in the four blocks of AABBBBAA-ABAB-BABA-BAAB-ABBA, which is assigned a number to each block. Will be found and each time a lottery will be selected and the babies will enter the study in order.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be blinded in two ways. Parents of infants and ward nurses will be blinded as to which group (control or intervention) they are in (unaware of the assignment of study groups) and the statistician who should analyze the data will be blinded to the type of intervention. In the analysis form, the intervention and control groups are identified by a specific code that only the researcher is aware of, and the statistical consultant does not know the definition of the codes.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Jomhory St. 60. No. 16

City

Qom

Province

Tehran

Postal code

3716766367

Approval date

2021-02-20, 1399/12/02

Ethics committee reference number

IR.TUMS.FNM.REC.1399.219

Health conditions studied**1****Description of health condition studied**

respiratory distress

ICD-10 code

J80

ICD-10 code description

Acute respiratory distress syndrome

Primary outcomes**1****Description**

respiratory distress

Timepoint

Before the intervention - four hours after the intervention and 8 hours after the intervention

Method of measurement

Respiratory Distress Assessment Questionnaire (Downs Score)

Secondary outcomes**1****Description**

Blood oxygen saturation

Timepoint

Before intervention - 4 hours after intervention and 8 hours after intervention
Method of measurement
Pulse oximetry device

Intervention groups

1

Description

Intervention group1: Infants who are exposed to the smell of breast milk. 3 cc of milk is taken daily from mothers to perform research; Sampling is done in the morning before breakfast to reduce the effect of odor on the milk in the mother's diet; Because the smell of food is secreted in milk 2-4 hours after consumption. Milk is stored in special plastic containers in the refrigerator. It is worth mentioning that breast milk will be used twice a day; ; Once at 8 o'clock in the morning and the next time at 12 noon, considering that the milk will be taken from the mothers only in the morning, the milk should be kept in the refrigerator for the evening shift. Prior to the intervention, the breast milk will be heated to 37 ° C by a water heater (Ben Marie).

Category

Treatment - Other

2

Description

Intervention group2: To prepare formula milk as a placebo (placebo group), use dry milk for premature babies with the Bebelac brand in the section, which was prepared just before use. Prior to the intervention, the formula milk (to body temperature) will be heated to 37 ° C by a water heater (Ben Marie).

Category

Placebo

3

Description

Control group: Does not receive any intervention

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Forqani Nekouei Hospital in Qom
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

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

No

Title of funding source

medical University Tehran

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
Tehran University of Medical Sciences
Full name of responsible person
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Professor
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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