Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 SHeikhshoaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 25 3288 0994

Email address
nursemosafer@gmail.com

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 2.36 / 2-37 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 AABB-BBAA-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

Fatemeh Sheikh Shoaei

Street address

Jomhory St. 60 - No. 16

City

Qom

Province

Ghoum

Postal code

3716766367

Phone

+98 25 3288 0994

Email

nursemosafer@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Jomhory Boulevard 60. No. 16

City

Qom

Province

Ghoum

Postal code

3716766367

Phone

+98 25 3288 0994

Email

nursemosafer@gmail.com

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

Akram Sadat Hosseini

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Tohid Square - Nosrat Sharghi St. - Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6693 7120
Fax
Email
tehrantarasht@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akram Sadat Hosseini
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Tohid Square - Nosrat Sharghi St. - Faculty of Nursing and Midwifery, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
00 (21) 66937120
Fax
Email
tehrantarasht@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Sheikh Shoaei
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Jomhory Boulevard 60. No. 16
City
Qom
Province
Ghoum
Postal code
3716766367
Phone
+98 25 3288 0994
Email
nursemosafer@gmail.com

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