Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of breast milk smell on weight and physiological criteria of premature infants

Protocol summary

Study aim
Determining the effect of smell of breast milk on weight and physiological criteria of premature infants

Design
A single blind randomized clinical trial with an intervention and a control group and a parallel group design.

Settings and conduct
The research is carried out in the NICU section of Imam Reza Hospital. The number of 150 newborns who have entry criteria are selected and after explaining the purpose of the research to parents and obtaining written consent from the parents are included in the study. The infants are then randomly divided into two groups of intervention and control

Participants/Inclusion and exclusion criteria
Inclusion criteria: The infant's age from the second birthday; the gestational age from 30 to 34 weeks; the fifth minute Apgar greater than 7; the baby's weight from 1000 to 1500 grams. Non-inclusion criteria: frequent apnea in neonates and the need for mechanical ventilation; secondary infection; seizure and intraventricular hemorrhage; infant death; Baby discharge and congenital anomalies.

Intervention groups
In the intervention group, breast milk is poured by syringe 1 CC around the mouth of the infant and rubbed with a pointed finger every 3 hours. In the control group, Sterile water is poured by syringe 1 CC around the mouth of the infant and rubbed with a pointed finger every 3 hours .

Main outcome variables
Infant weight; Percentage of arterial blood saturation; Neonatal heart rate; Neonatal respiratory rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001162N25**
Registration date: **2019-08-31, 1398/06/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-31, 1398/06/09**
Update count: **0**

Registration date
2019-08-31, 1398/06/09

Registrant information

Name
Ashraf Mohammadzadeh

Name of organization / entity
Neonatal Research Center of Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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+98 51 1852 1121

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-21, 1398/02/01

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of breast milk smell on weight and physiological criteria of premature infants

Public title
The effect of breastfeeding on the weight of newborns
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Beginning in day 3 30 to 34 weeks gestational age 5-minute apgar more than 7 birth weight between 1000 to 1500 grams
Exclusion criteria:
frequent apnea in neonates and the need for mechanical ventilation secondary infection seizure and intravenous bleeding anomalies Congenital
Age
From **2 days** old to **30 days** old
Gender
Both

Phase
1
Groups that have been masked

- Participant

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
This study will be carried out with simple randomization. In this way, 150 newborns with entry criteria by stratified randomization are selected and after explaining the purpose of the study, they will enter the parents to obtain written consent from their parents. The infants are divided into two groups of intervention and control.
Blinding (investigator's opinion)
Single blinded
Blinding description
Considering that the babies do not have the necessary knowledge in this regard and the mothers have not been informed about this study, the study is therefore one-way blind and only the researcher who is performing the study knows.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Ghoreyshi Building- Daneshgah St- Mashhad- Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Approval date
2019-04-08, 1398/01/19
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.734

Health conditions studied

1

Description of health condition studied
preterm infants
ICD-10 code
P07.3
ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Weight of premature infants
Timepoint
The baby's weight is monitored and recorded daily and from the second day of birth (the first day of sampling), half an hour after breast feeding to the baby's mouth.
Method of measurement
balance

2

Description
Percentage of arterial blood saturation
Timepoint
the duration of one week is 8 hours, 8, 14 and 22 hours every 8 hours and recorded in daily information. The remaining days are also checked for 8 weeks at 8, 14 and 22 hours for 1 week.
Method of measurement
questionnaire

3

Description
Infant heart rate
Timepoint
the duration of one week is 8 hours, 8, 14 and 22 hours every 8 hours and recorded in daily information. The remaining days are also checked for 8 weeks at 8, 14 and 22 hours for 1 week.
Method of measurement
questionnaire

4

Description

Infant respiratory rate

Timepoint

the duration of one week is 8 hours, 8, 14 and 22 hours every 8 hours and recorded in daily information. The remaining days are also checked for 8 weeks at 8, 14 and 22 hours for 1 week.

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: preterm newborns with birth weight between 1000-1500 gr. In the intervention group, breast milk is poured by syringe 1 CC around the mouth of the infant and rubbed with a pointed finger every 3 hours.

Category

Treatment - Drugs

2

Description

In the control group, Sterile water is poured by syringe 1 CC around the mouth of the infant and rubbed with a pointed finger every 3 hours .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Fatemeh Parvin

Street address

Imam Reza hospital, Ibn Sina Ave

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Email

parvinf1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh Parvin

Position

Nurse

Latest degree

Master

Other areas of specialty/work

Pediatrics

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Imam Reza hospital, Ibn Sina avenue

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Ashraf Mohammadzadeh

Position
professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Master

Other areas of specialty/work
Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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

Title and more details about the data/document
Some of the patient information present in the questionnaire will be available to people via e-mail. Corresponder email: nrc@mums.ac.ir

When the data will become available and for how long
Start the access period after printing the results

To whom data/document is available
En Available to academic and academic researchers

Under which criteria data/document could be used
After publishing it as a paper for the public and researchers from academic medical institutions

From where data/document is obtainable
google- ISI

What processes are involved for a request to access data/document
In search sites, the use of the effect of breastfeeding smell,Physiological criteria, preterm newborn

Comments