

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1852 1121

##### Email address

mohamadzadeha@mums.ac.ir

#### 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

**City**  
Mashahd

**Province**  
Razavi Khorasan

**Postal code**  
9137913316

**Phone**  
+98 51 3852 1121

**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

**Street address**  
Ghoreyshi building, Daneshgah Avenue

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parvinf1@mums.ac.ir

**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

**Street address**  
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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Neonatal Intensive Care Unit, Imam Reza hospital, Ibn Sina Ave-

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## Person responsible for updating data

### 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

**Street address**

Neonatal Intensive Care Unit, Imam Reza hospital, Ibn Sina avenue

**City**

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**Province**

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**Postal code**

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**Phone**

+98 51 3852 1121

**Email**

parvinf1@mums.ac.ir

## 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. Correspondent 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**