

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of lullaby on Volume, fat, total protein and albumin of breast milk in mothers of premature infants admitted to neonatal intensive care unit.

#### Protocol summary

##### Study aim

The effect of lullaby on the volume, fat, total protein and albumin of breast milk in preterm neonatal mothers hospitalized in neonatal intensive care unit of Ayatollah Rohani

##### Design

A randomized controlled clinical trial with parallel groups, without blinding

##### Settings and conduct

The study population was mothers of premature infants hospitalized in the neonatal intensive care unit of Rohani hospital in Babol. and three groups of 30 in the first group on the first and sixth day of mother's milk sample, in the second group on the first day of the mother's milk sample and on the sixth day the sampling was repeated after listening to lullaby. In the third group, the mother was sampled on the first day after routine lactation training and listening to the lullaby for 30 minutes with the mother looking at her infant's picture, and again on the sixth day.

##### Participants/Inclusion and exclusion criteria

1) mother's willingness to participate in research 2) mother's breastfeeding 3) mother's ability to breastfeed at least once a day 4) intrauterine age 37-34 weeks 5) lack of anatomical problems in the breast such as nipple and fissure and mastitis 6) A physician's written instruction to allow breastfeeding by the mother 7) Not to have a previous pregnancy that may even lead to miscarriage.

##### Intervention groups

In this study we will have three groups: Group 1) Routine breastfeeding training only Group 2) Routine Breastfeeding Training with Lullaby for Mother, Group 3) Routine breastfeeding training with lullaby voice for mother with baby photo of mother

##### Main outcome variables

The variables of this study are: breast milk volume,

breast milk triglyceride, breast milk cholesterol, breast milk total protein, breast milk albumin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191114045439N1**

Registration date: **2020-01-14, 1398/10/24**

Registration timing: **prospective**

Last update: **2020-01-14, 1398/10/24**

Update count: **0**

##### Registration date

2020-01-14, 1398/10/24

##### Registrant information

##### Name

Somayyeh Sefidhaji

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3233 7506

##### Email address

s.sefidhaji@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-21, 1398/11/01

##### Expected recruitment end date

2020-07-22, 1399/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of lullaby on Volume, fat, total protein and albumin of breast milk in mothers of premature infants admitted to neonatal intensive care unit.

**Public title**  
The effect of lullaby on Volume, fat, total protein and albumin of breast milk in mothers of premature infants admitted to neonatal intensive care unit.

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
mother's willingness to participate in research mother's breastfeeding mother's ability to breastfeed at least once a day intrauterine age 37-34 weeks no anatomical problems in the breast such as nipple and fissure and mastitis Written doctor's order that the mother be allowed to breast-feed Not have a previous pregnancy that may even lead to abortion  
**Exclusion criteria:**  
1) mothers having cigarettes and addiction 2) use of drugs that affect milk production 3) active mothers with tuberculosis 4) mothers with AIDS 5) mothers who have undergone breast surgery 6) use Mothers who have hearing problems 7) using mothers who have postpartum depression or experiencing a life-threatening crisis 8) using mothers who are using nutritious ingredients 9) using mothers who have dietary and vegetable diets.

**Age**  
No age limit

**Gender**  
Female

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Given that the study population does not enter the study at the same time, and the researchers do not anticipate which group of individuals will belong to the study, randomization and hiding are used. To assign mothers of target group to one of three study groups (A, B and C), Block Randomization method is used, using random list generated by Random Allocation Software. Random will be put into opaque envelopes (concealment) until the assignment of people to groups is unpredictable.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

National Ethics Committee on Biomedical Research

##### Street address

13th Floor, Block A, Headquarters of the Ministry of Health and Medical Education, , Iran Sima Ave, between South Flamak and Zarafshan, , Quds Town (West), Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1467664961

#### Approval date

2019-11-09, 1398/08/18

#### Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.217

## Health conditions studied

### 1

#### Description of health condition studied

Volume, Fat, Total Protein, and Albumin of Breastfeeding Mothers Hospitalized in Neonatal Intensive Care Unit

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

breast milk volume

#### Timepoint

The first day of study and the sixth day of study in all three groups

#### Method of measurement

By the graduated container

### 2

#### Description

triglyceride

#### Timepoint

The first day of study and the sixth day of study in all three groups

#### Method of measurement

By spectrophotometer

### 3

**Description**

cholesterol

**Timepoint**

The first day of study and the sixth day of study in all three groups

**Method of measurement**

By spectrophotometer

### 4

**Description**

total protein

**Timepoint**

The first day of study and the sixth day of study in all three groups

**Method of measurement**

By spectrophotometer

### 5

**Description**

albumin

**Timepoint**

The first day of study and the sixth day of study in all three groups

**Method of measurement**

By spectrophotometer

## Secondary outcomes

### 1

**Description**

We have no secondary consequence.

**Timepoint**

21/1/2020

**Method of measurement**

The volume of breast milk is measured by a graduated container in milliliters. Breast milk triglyceride, breast milk cholesterol, total breast milk protein and albumin were calculated by standard kit and UK Spectrophotometer (UNICO 9344) with a precision measurement of mg / dl.

## Intervention groups

### 1

**Description**

Intervention group: A group that listens to lullaby with routine training.

**Category**

Other

### 2

**Description**

Intervention group: A group that looks at their pre-baby photo taken during lactation, in addition to listening to lullaby.

**Category**

Other

### 3

**Description**

Control group: Who receive only routine training.

**Category**

Other

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Ayatollah Rouhani Hospital

**Full name of responsible person**

Somayyeh Sefidhagi

**Street address**

Ayatollah Rouhani Hospital- Keshavarz Boulevard- Babol

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717641367

**Phone**

+98 11 3223 8301

**Email**

sshagi1362@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Vice chancellor for research, Babol University of Medical Sciences

**Full name of responsible person**

dr. Reza Ghadimi

**Street address**

Keshavarz Boulevard, Babol University of Medical Sciences, Vice chancellor for research

**City**

Babol

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**Email**

rezaghadimi@yahoo.com

**Web page address**

<https://research.mubabol.ac.ir>

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

**organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Somayyeh Sefidhagi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Babol Medical University

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**Province**

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

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Somayyeh Sefidhagi

**Position**

Nurse

**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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**Full name of responsible person**

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**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information.

**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