

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison effect of two methods of pacifier sucking And Mother's finger on Oral Feeding Skills in Premature Infants

#### Protocol summary

##### Study aim

Evaluation effect of two methods of pacifier sucking And Mother's finger on Oral Feeding Skills in Premature Infants

##### Design

Infants aged 31 to 33 weeks with a minimum weight of 1350 select the available samples based on the specification of the study unit. Randomized blocking face is divided into three groups: sucking pacifier, mother finger and control group receiving routine care. This study is a randomized clinical trial with control group with parallel groups with sample size of 50 people in each group.

##### Settings and conduct

Procedure: In the first group, the pacifier enters the baby's mouth before gavage and in the second group, the mother puts her finger in the baby's mouth. Neonates are observed 2 minutes before, during and 2 minutes after the intervention. This procedure is performed three times a day (early morning, noon and afternoon and each time for 5 minutes) for at least 10 days. And the control group receives routine care in the ward. It is a questionnaire measuring tool (PIBBS). Due to one-blind study, a nurse performs other than the primary outcome researcher (PIBBS) at the end of the study at Babol Ayatollah Rouhani Hospital with no information on how the infants are assigned to the group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age 31 to 33 weeks, minimum weight interval 1350 g, gavage feeding  
Exclusion criteria: any congenital malformations, especially in the jaw, mouth and palate, respiratory problems, heart

##### Intervention groups

Non-Nutritional Sucking Group, Immediately Before Gavage, Putting Nipple in Baby's Mouth - Non-Nutritional Sucking Mother's Group, Immediately Before Gavage, Breast Feeding for 5 Minutes in Newborn Mouth-Control Group Receives Routine Care.

#### Main outcome variables

Facilitation Score and Duration of Oral Nutrition, Breast Sucking Time

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191116045460N1**

Registration date: **2020-01-11, 1398/10/21**

Registration timing: **prospective**

Last update: **2020-01-11, 1398/10/21**

Update count: **0**

##### Registration date

2020-01-11, 1398/10/21

##### Registrant information

##### Name

Fatemeh Shaki

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 9592

##### Email address

f.shaki@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**  
Comparison effect of two methods of pacifier sucking  
And Mother's finger on Oral Feeding Skills in Premature  
Infants

**Public title**  
Comparison effect of two methods of pacifier sucking  
And Mother's finger on Oral Feeding Skills in Premature  
Infants

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Gestational age between 31 and 33 weeks Minimum  
weight of intervention time, 1350 g Feeding by gavage  
No mother's addiction to alcohol or drugs  
**Exclusion criteria:**  
Any congenital malformations, especially in the jaw,  
mouth and palate Including respiratory problems such as  
bronchopulmonary dysplasia, cardiac, convulsive, grade  
4 and 3 intraventricular hemorrhage

**Age**  
From **1 day** old to **28 days** old

**Gender**  
Both

**Phase**  
N/A

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

**Sample size**  
Target sample size: **150**

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

**Randomization description**  
Subjects will be randomly assigned to the permissive  
block method after applying entry and exit criteria. The  
randomization unit will be individual. By using a  
randomly selected block list, infants will be placed in the  
non-nutritious suckling group and the other group in the  
non-nutritious sucking group and the control group.  
Given that the type of intervention is such that we  
cannot blind the participants, we did our best to evaluate  
the outcome and evaluate the PIBBS by someone who  
did not know the sample allocation.

**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

Ethics Committee of Babol University of Medical  
Sciences

##### Street address

Keshavarz Ave, Ayatollah Rouhani Hospital

##### City

babol

##### Province

Mazandaran

##### Postal code

4941779355

#### Approval date

2019-11-09, 1398/08/18

#### Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.216

## Health conditions studied

### 1

#### Description of health condition studied

The condition of premature infants

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Feeding behavior score

#### Timepoint

Measurement of feeding behavior 10 days after  
intervention

#### Method of measurement

Breastfeeding Behavior

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: non-nutritional suckling infants  
group in which preterm infants aged 31 to 33 weeks with  
a minimum body weight of 1350 g were selected and  
three times daily for ten days a pacifier (Pars Silicon  
Company product called Mina Bib Cover) Specifically) by  
the mother entered the baby's mouth.

#### Category

Behavior

## 2

### Description

Intervention group 2: Non-nutritious suckling infants group in this group were preterm infants aged 31 to 33 weeks with a minimum weight of 1350 g and three times daily for 10 days.

### Category

Behavior

## 3

### Description

control group: In this group, preterm infants aged 31 to 33 weeks with a minimum weight of 1350 g were selected and received routine care.

### Category

Behavior

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Babol Ayatollah Rouhani Hospital

##### Full name of responsible person

Fatemeh shaki

##### Street address

Ayatollah Rouhani Hospital, Keshavarz Ave.

##### City

Babol

##### Province

Mazandaran

##### Postal code

4941779355

##### Phone

+98 11 3223 8303

##### Fax

##### Email

fatemeshaki1980@gmail.com

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Dr. Reza Ghadimi

##### Street address

Keshavarz Avenue

##### City

Babol

##### Province

Mazandaran

##### Postal code

۴۷۱۷۶-۴۷۷۵۴

##### Phone

+98 11 3223 8303

##### Fax

##### Email

rezaghadimi@yahoo.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

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

Fatemeh Shaki

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Gharbi Keshavarz Street

##### City

Aliabad Katul

##### Province

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##### Postal code

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##### Phone

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##### Email

fatemeshaki1980@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Fatemeh Shaki

##### Position

student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

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**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Fatemeh Shaki

**Position**

student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Gharbi Keshavarz Street

**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**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available