

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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 suckling 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.

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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

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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

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

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Person responsible for scientific inquiries

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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

Bachelor

Other areas of specialty/work

Nursery

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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