Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparative Study of the Effect of Oral Stimulation and Non-Oral Stimulation Intervention in Premature Infant on start time, the Time of Independent Oral Nutrition, Weight Gain and length of stay in hospital

Protocol summary

Study aim

Comparison of the effect of oral and non-oral intervention of preterm infants on the time of achieving independent oral feeding, weight gain and time of hospital discharge

Design

This study is a RCT. The study population was premature infants aged 28-32 weeks. The method of selecting the subjects after applying the entry and exit criteria is random allocation. The personal and medical information of the subjects is recorded in the prepared questionnaire based on the medical records available in the neonatal intensive care unit and by asking questions from the parents.

Settings and conduct

This study is performed in NICU of Om Al-Banin Hospital.

Participants/Inclusion and exclusion criteria

1. Be born between 28-32 weeks of gestation. 2. Receive nutrition through the tube 3. Their birth weight is between 1000-2000 grams 4. Have physiological stability (stability in spo2, Hr, RR) at the beginning of nutritional stimuli. 5. Oral irritation and the onset of feeding in these infants do not alter the autonomic system [skin color, heart rate, or respiration rate]. 6. Apgar score above 6 in 5 minutes 7. Newborns without congenital anomalies and obvious chromosomal abnormalities 8. No oral lesions such as candidiasis 9. No lip and mouth abnormalities such as cleft lip and palate

Intervention groups

Oral stimulation group with the method: PIOMI. The non-oral stimulation group with FIELD technique is another group that will be performed by field massage every day.Control Group:Will receive NICU Routine Care.

Main outcome variables

The timing of the onset of oral feeding and reach 8 independent oral feedings in infants in the intervention and control groups will be assessed. The weight of the newborns and age of hospital discharge will be assessed on a daily basis and the average will be compared in the intervention and control groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210224050479N1**
Registration date: **2021-03-03, 1399/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-03, 1399/12/13**
Update count: **0**

Registration date

2021-03-03, 1399/12/13

Registrant information

Name

najme zabihi torbati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3605 9029

Email address

zabihitn1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-28, 1399/12/10

Expected recruitment end date

2021-08-01, 1400/05/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Study of the Effect of Oral Stimulation and Non-Oral Stimulation Intervention in Premature Infant on start time, the Time of Independent Oral Nutrition, Weight Gain and length of stay in hospital

Public title
Comparative Study of the Effect of Oral Stimulation and Non-Oral Stimulation Intervention in Premature Infant on start time, the Time of Independent Oral Nutrition, Weight Gain and length of stay in hospital
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
1. Be born between 28 and 32 weeks of gestation.2. Receive nutrition through the tube3. Their birth weight is between 1000-2000 grams4. Have physiological stability (stability in spo2, Hr, RR) at the beginning of nutritional stimulation.5. Oral stimulation and the onset of feeding in these infants do not alter the autonomic system [skin color, heart rate, or respiration rate].6. Apgar score above 6 in 5 minutes7. Newborns without congenital anomalies and obvious chromosomal abnormalities8. No oral lesions such as candidiasis9. No lip and mouth abnormalities such as cleft lip and palate
Exclusion criteria:
1. NPO of the baby in case of symptoms such as fever, respiratory distress, muscle stiffness, frequent vomiting for one day and more2. Diagnosis of cases such as intraventricular hemorrhage, necrotizing enterocolitis, open arterial duct, sepsis, acute lung disease or severe anemia by a physician during the days of interventions3. The need for surgery during the days of interventions4. Transfer the baby to other centers5. Infant death6. Lack of cooperation of the mother in performing the interventions7. Maternal addiction8. Physiological instability (spo2, Hr, RR) during a day and night so that he can not receive one pumice massage or two field massage.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
It was used to allocate infants to intervention and control groups by random block method with a volume of 3 (numbers 1 to 90) according to the lottery in closed envelopes. Random block sampling is a method of randomization that ensures that at almost every point in a study, an almost equal number of participants are assigned to all comparison groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The analyst will be unaware of the intervention and control groups.
Placebo
Not used
Assignment
Other
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
Doktora Crossroads-School of Nursing and Midwifery
City
mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Approval date
2021-01-28, 1399/11/09
Ethics committee reference number
IR.MUMS.NURSE.REC.1399.081

Health conditions studied

1

Description of health condition studied
The study is about premature infants and the importance of achieving independent oral nutrition and weight gain.
ICD-10 code
p07
ICD-10 code description
اختلالاتی که به کوتاه بودن دوران حاملگی یا وزن کم زمان تولد مربوط باشد

Primary outcomes

1

Description
The timing of the onset of oral feeding in infants in the intervention and control groups will be assessed.
Timepoint

When to start oral feeding for the first time

Method of measurement

Record the age of the infant at the time of starting oral feeding in a questionnaire

2

Description

The time of reach to independent oral feedings in the infants of the intervention and control groups will be evaluated.

Timepoint

Time to reach 8 times independent oral feeding

Method of measurement

Record the age of the infant at the time of reaching 8 times of independent oral feeding in a questionnaire

Secondary outcomes

1

Description

The weight of the newborns will be assessed on a daily basis and the average will be compared in the intervention and control groups.

Timepoint

The weight during the study on a daily

Method of measurement

Weight will measure with scales

2

Description

The age of hospital discharge in infants in the intervention and control groups will be compared.

Timepoint

The time of discharge

Method of measurement

Record the age of the infant at the time of discharge in a questionnaire

Intervention groups

1

Description

Intervention group: Oral stimulation group with PIOMI method: "Oral stimulation before feeding" program is a five-minute oral-motor intervention. In this program, stimuli are applied to oral structures including cheeks, gums, lips, tongue. It is served by gavage once a day before feeding. Oral ostomy intervention for 7 consecutive days without interruption for each infant is performed first by the researcher and after education to the mother by the mother. The 5-minute stimulation program includes 3 minutes of stretching and cheek massage and 2 minutes (non-nutritional sucking (NNS)).

Category

Rehabilitation

2

Description

Intervention group: Non-oral stimulation group with FIELD technique is another group that will be performed by field field massage method per day. Each 15-minute period (before feeding) consists of three 5-minute phases in which the infant is placed in a supine position on the abdomen at the beginning and end, and the fingers of both hands are touched with a gentle pressure with the smooth part of the fingers. In these two phases, one of the following five areas is touched every minute (12 touches in 5 seconds): from the tip of the head down to the sides of the face to the neck and vice versa, from the back of the neck across the shoulders and vice versa , From the upper back to the bottom to the waist and vice versa, from the thighs down to the ankles and vice versa, from the shoulders to the wrists and vice versa. In the middle phase, the infant was lying flat on its back and 6 passive extension-flexion movements (one every 10 seconds) were given to these five areas, respectively: right arm, left arm, right leg, left leg, and both legs. This protocol lasts for 7 days

Category

Rehabilitation

3

Description

Control group: NICU routine care including non-nutritional sucking and kangaroo care will be given to the baby twice a day.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Om Al Banin hospital

Full name of responsible person

Najme Zabihi Torbati

Street address

Behjat18 street

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Province

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9878965754

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zabihitn1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr 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
Dr Naghme Razaghi
Position
Assistant Proffessor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Nurse
Latest degree
Bachelor
Other areas of specialty/work
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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

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

Publish as an article

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Use of data and results with reference

From where data/document is obtainable

Correspondence with the project manager Dr. Naghmeh Razaghi

What processes are involved for a request to access data/document

Request via email

Comments