

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Investigation of the effectiveness of Premature Infant Oral Motor Intervention on feeding performance of infants admitted to the NICU

#### Protocol summary

##### Study aim

Investigation of the effectiveness of Premature Infant Oral Motor Intervention on feeding performance of infants admitted to the NICU

##### Design

Clinical trials with intervention and control group, parallel-group design, based on the individual, double-blind, randomized, and the sample size is 20 premature infants.

##### Settings and conduct

This study is a double-blind randomized clinical trial because Both parents of participants and the outcome evaluator are unaware of the allocation of study groups. The infants will be randomly assigned to two intervention and control groups. the intervention group will receive oral motor stimulations for 5 minutes per day for 7 consecutive days and the control group will receive routine nursing care services. This study will be performed in the NICU of Imam Khomeini Hospital in Ahvaz.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Born with a gestational age of 29-32 weeks, The birth weight is between 1000 to 2000 grams and Physiological stability at the time of receiving oral stimulations. exclusion criteria: the existence of chronic medical complications, the existence of congenital anomalies(eg, heart, oral, etc), the existence of Necrotizing enter colitis(NEC), the existence of a brain injury (including intra-ventricular hemorrhage greater than grade 1), the existence of a history of prenatal illicit drug exposure, and receiving assistive ventilation (other than high-flow nasal cannula).

##### Intervention groups

Infants in the intervention group will receive PIOMI for 5 minutes per day for 7 consecutive days and the infants in the control group will receive routine nursing care services.

##### Main outcome variables

Early Feeding Skills (EFS) Assessment score in preterm

infants; Feeding Progression; Sucking frequency; Feeding proficiency; The transition time from gavage to independent oral feeding; Length of hospital stay

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200908048663N1**

Registration date: **2020-11-21, 1399/09/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-21, 1399/09/01**

Update count: **0**

##### Registration date

2020-11-21, 1399/09/01

##### Registrant information

##### Name

Rezvan Isazadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4263 0635

##### Email address

isazadeh.r@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-11-11, 1399/08/21

##### Expected recruitment end date

2021-02-09, 1399/11/21

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigation of the effectiveness of Premature Infant Oral Motor Intervention on feeding performance of infants admitted to the NICU

**Public title**  
Investigation of the effectiveness of Premature Infant Oral Motor Intervention on feeding performance of infants admitted to the NICU

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 Born with a gestational age of 29-32 weeks The birth weight is between 1000 to 2000 grams Physiological stability at the time of receiving oral stimulations  
**Exclusion criteria:**  
 Existence of chronic medical complications Existence of congenital anomalies(eg, heart, oral, etc) Existence of Necrotizing enter colitis(NEC), Existence of a brain injury (including intra-ventricular hemorrhage greater than grade 1) Existence of history of prenatal illicit drug exposure Receiving assistive ventilation (other than high-flow nasal cannula)

**Age**  
From **203 days** old to **224 days** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **20**

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

**Randomization description**  
Randomization is simple and using the <https://www.randomizer.org> site.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Infants' mothers and an individual other than the researcher. The intervention is performed by the principal researcher and the evaluations are performed by an individual other than the researcher. In this study, the outcome evaluator does not know about the grouping of infants

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

##### Street address

Golestan St

##### City

Ahvaz

##### Province

Khouzestan

##### Postal code

15794-61357

#### Approval date

2019-07-06, 1398/04/15

#### Ethics committee reference number

IR.AJUMS.REC.1398.265

## Health conditions studied

### 1

#### Description of health condition studied

Dysphagia in premature infants

#### ICD-10 code

R13.19

#### ICD-10 code description

Other dysphagia

## Primary outcomes

### 1

#### Description

The Early feeding skills (EFS) assessment instrument score in preterm infants

#### Timepoint

At the time of the first oral feeding, the time of discharge and one week after discharge

#### Method of measurement

The Early feeding skills (EFS) assessment instrument in preterm infants (This checklist contains 26 items that each item can score 1, 2, or 3)

### 2

#### Description

Feeding Progression

#### Timepoint

During intervention

#### Method of measurement

Record of the number of days since the onset of oral feeding until the achievement of independent oral feeding

### 3

#### **Description**

The transition time from gavage to independent oral feeding

#### **Timepoint**

Daily

#### **Method of measurement**

Record the number of days since the onset of gavage feeding until the achievement of independent oral feeding

## **Secondary outcomes**

### 1

#### **Description**

Maintenance

#### **Timepoint**

One week after discharge from the hospital

#### **Method of measurement**

The Early Feeding Skills (EFS) Assessment instrument in preterm infants

### 2

#### **Description**

Length of hospital stay

#### **Timepoint**

Daily

#### **Method of measurement**

Record the number of days from the time the infant is admitted to the NICU until discharge

### 3

#### **Description**

Weight gain

#### **Timepoint**

At the time of enrollment, the first oral feeding, independent oral feeding, and the time of discharge from the hospital

#### **Method of measurement**

Put the infant on a digital balance and record the infant's weight to gram

### 4

#### **Description**

Feeding proficiency

#### **Timepoint**

From the initiation of oral feeding to the time of hospital discharge

#### **Method of measurement**

% ml taken during the first 5 min/ml prescribed

### 5

#### **Description**

Sucking frequency

#### **Timepoint**

From the initiation of oral feeding to the time of hospital discharge

## **Method of measurement**

Number of sucking per minutes

## **Intervention groups**

### 1

#### **Description**

Intervention group: 5 Minute massage in and around the mouth using a PIOMI protocol, once a day for seven days

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: Receiving routine medical and nursing services. They do not receive any speech therapy intervention

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Khomeini Hospital

##### **Full name of responsible person**

Rezvan Isazadeh

##### **Street address**

Azadegan St

##### **City**

Ahvaz

##### **Province**

Khouzestan

##### **Postal code**

15794 -61357

##### **Phone**

+98 61 3222 2818

##### **Email**

Isazadeh.r@ajums.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

Dr. Mohammad Badwi

##### **Street address**

Golestan St

##### **City**

Ahvaz

##### **Province**

Khouzestan

##### **Postal code**

61357-15794

##### **Phone**

+98 61 3222 2818

**Email**

info@ajums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ahvaz 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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Negin Moradi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Speech therapy

**Street address**

Golestan St

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

15794-61357

**Phone**

+98 61 3374 3101

**Email**

neginmoradist@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Rezvan Isazadeh

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Speech therapy

**Street address**

Golestan St

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

15794-61357

**Phone**

+98 61 3222 2818

**Email**

Isazadeh.r@ajums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Rezvan Isazadeh

**Position**

MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Speech therapy

**Street address**

Golestan St

**City**

Ahvaz

**Province**

Khouzestan

**Postal code**

15794-61357

**Phone**

+98 61 3222 2818

**Email**

Isazadeh.r@ajums.ac.ir

## 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**

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