

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation of the Premature Infant Oral Motor Intervention (PIOMI) on Oral Feeding Progression in Preterm Infants With Gestational Age between 26-29weeks.

Protocol summary

Study aim

Comparison of Weight at the time of reach one, four, eight and discharge of hospital; Gestational Age at the time of reach one, four, eight and discharge of hospital; feeding progression and length of hospital stay between control group and intervention group.

Design

Clinical trials with intervention and control group; parallel group design; Double blind, and randomized

Settings and conduct

This study is related to oral motor skills and oral nutrition of premature infants. We have collected data in Akbarabadi and Arash Hospital in Tehran.. The infants were randomly assigned into two intervention and control groups. The intervention group received 5 minutes of oral massage daily. The doctor determined the amount and manner of receiving milk and the time of discharge. The doctor was unaware of the grouping of babies

Participants/Inclusion and exclusion criteria

Inclusion criteria: Premature infants with gestational age(GA) between 26-29 Physiological stability at the onset of intervention Parental consent Exclusion criteria: Failure to get gavage before the end of the 29th week (GA) chronic illness or genetic problems

Intervention groups

The intervention group received 5 minutes of oral massage per day for 10 days, according to Premature Infants Oral Motor Intervention (PIOMI) The control group only receives hospital routine services.

Main outcome variables

Feeding progression; Duration of transmission from oral gavage to full oral feeding; discharge from the hospital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180410039260N1**

Registration date: **2018-07-06, 1397/04/15**

Registration timing: **retrospective**

Last update: **2018-07-06, 1397/04/15**

Update count: **0**

Registration date

2018-07-06, 1397/04/15

Registrant information

Name

Hadise Ghomi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7795 6924

Email address

Ha.ghomi@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

2017-08-01, 1396/05/10

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

empty

Scientific title

Evaluation of the Premature Infant Oral Motor

Intervention (PIOMI) on Oral Feeding Progression in Preterm Infants With Gestational Age between 26-29weeks.

Public title

evaluation of PIOMI on oral feeding in preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Premature infants with gestational age between 26-29 weeks Physiological stability at the onset of intervention Apgar score higher than 6 in the fifth minute after birth Parental consent

Exclusion criteria:

Chronic genetic and medical problems Parental dissatisfaction No received of nutrition through gavage until the end of the 29th week of GA

Age

From **182 days** old to **203 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **30**

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 doctors The doctor examines the oral and nutritional capacity. The doctor 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 university of social welfare and rehabilitation science

Street address

University of social welfare and rehabilitation science,

Koodakyar Ave, Daneshju blv, Evin, Trlehran

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Approval date

2017-06-18, 1396/03/28

Ethics committee reference number

IR.USWR.REC.1396.85

Health conditions studied**1****Description of health condition studied**

Feeding in Premature infants

ICD-10 code

P92

ICD-10 code description

Feeding problems of newborn

Primary outcomes**1****Description**

Feeding progression was calculated from the day when oral feedings were initiated to the day when full oral feedings were attained. Fewer days indicated faster progression.

Timepoint

postmenstrual age(PMA) on the time of one, fore and full oral feeding

Method of measurement

PMA , days

2**Description**

Length of hospital stay

Timepoint

Gestational age in birth time and discharge time (day)

Method of measurement

Day

Secondary outcomes**1****Description**

Weight on the time of one, fore and full oral feeding and discharge

Timepoint

Time of one, fore and full oral feeding and discharge

Method of measurement

Digital Balance in grams

Intervention groups

1

Description

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

Category

Rehabilitation

2

Description

Control group: Medical and nursing services provided in all hospitals. There is no speech therapy intervention in these two hospitals

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان اکبرآبادی

Full name of responsible person

Ali Mazoury

Street address

Akbarabadi Hospital, Raees Abdollahi Street, Molavi street

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2

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Shahin Nariman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Fariba Yadegari

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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

University of social welfare and rehabilitation sciences

Proportion provided by this source

50

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Hadise Ghomi

Position

Master student of speech therapy

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Unidentifiable infants data, summary of treatment protocol, statistical analysis will be fully published.

When the data will become available and for how long

From 2018

To whom data/document is available

Everyone interested in this topic

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Researcher email address: hh.ghomi@yahoo.com

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

There is no particular process. After receiving the email, the information will be sent.

Comments