Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect between Premature Infant Oral Motor Intervention (PIOMI) and Maternal stress with neonatal outcomes in preterm neonates

Protocol summary

Study aim
The relationship between oral motor intervention of preterm infants and neonatal outcomes in preterm infants admitted to neonatal intensive care unit

Design
The available sampling method will be randomization of permutation blocks with a volume of four units in each block. Sample size: 62 people

Settings and conduct
This study is a randomized clinical trial. The study population included all premature infants (diagnosed by a doctor) admitted to the neonatal intensive care unit who referred to Ayatollah Taleghani Hospital in Arak in 1400.

Participants/Inclusion and exclusion criteria
Premature infants Inclusion criteria: Premature infants aged 27 to 33 weeks of gestation who are admitted to the neonatal intensive care unit, consent of the infants' parents Exclusion criteria: Infants with cleft palate, cleft lip and congenital malformation (based on the information recorded in the file), sepsis, heart disease, necrotizing enterocolitis, grade 3 and 4 intraventricular hemorrhage

Intervention groups
Oral motor intervention (PIOMI) in the intervention group is performed after the start of oral feeding. The control group receives routine care.

Main outcome variables
Neonatal Outcomes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220124053823N1**
Registration date: **2022-02-16, 1400/11/27**
Registration timing: **prospective**

Last update: **2022-02-16, 1400/11/27**
Update count: **0**

Registration date
2022-02-16, 1400/11/27

Registrant information

Name
Fatemeh Shahjuee

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 86 3313 6055

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-06, 1400/12/15

Expected recruitment end date
2022-07-06, 1401/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect between Premature Infant Oral Motor Intervention (PIOMI) and Maternal stress with neonatal outcomes in preterm neonates

Public title
"Effect of Premature Infant Oral Motor Intervention in

neonatal outcomes"; "Effect of Maternal stress in outcomes in neonatal outcomes"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All premature infants aged 27 to 33 weeks of gestation
Hospitalized in the neonatal intensive care unit
Satisfaction of parents of infants

Exclusion criteria:

Infants with cleft palate, cleft lip and congenital malformation (based on information recorded in the file)
Septicemia heart disease Necrotizing enterocolitis Grade 3 and 4 intraventricular hemorrhage

Age

From **189 days** old to **231 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 arak University of Medical Sciences

Street address

Third Floor., Imam Musa Kazem Building., University Complex of the Great Prophet (PBUH)., Basij Square., Sardasht

City

Arak

Province

Markazi

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Approval date

2021-09-19, 1400/06/28

Ethics committee reference number

IR.ARAKMU.REC.1400.130

Health conditions studied

1

Description of health condition studied

Premature Infant

ICD-10 code

P07.31

ICD-10 code description

Preterm newborn, gestational age 28 completed weeks

Primary outcomes

1

Description

Maternal stress score in the standard perceived stress questionnaire of Cohen et al

Timepoint

Before the intervention and three days after the intervention and the day of discharge

Method of measurement

Perceived stress standard questionnaire

2

Description

Nutritional tolerance score in the daily chart

Timepoint

قبل از آغاز مداخله و سه روز بعد از مداخله و روز ترخیص

Method of measurement

View

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:When oral feeding is started in premature infants, the study begins. The volume of milk tolerated will be charted each day and the amount reached to the full volume of milk, ie equivalent to 3 cc per weight, will be calculated as a full fed full cut off. After starting oral feeding, the intervention method was stimulation in the cheeks for 30 seconds and in each species twice, stimulation in the lips for 30 seconds once, budding of the lips for 30 seconds once, gingival stimulation for 30 seconds twice, stimulation of the lateral sides of the tongue and cheeks for 15 seconds once, stimulation of the middle septum of the tongue and palate for 30 seconds twice and finally non-nutritional sucking with a pacifier for two minutes and the rate of respiration and Maternal stress will also be assessed as a questionnaire. Then, the duration of full feeding and the volume of nutritional tolerance and the score of the standard perceived stress questionnaire all before the intervention and three days after the intervention and the day of discharge (to check the

reduction of maternal stress) in the checklist for each patient and finally The length of hospital stay is recorded.

Category

Rehabilitation

2

Description

Control group: Parents and children receive only routine hospital care. Then, the duration of full feeding and the volume of nutritional tolerance and the score of the standard perceived stress questionnaire all before the intervention and three days after the intervention and the day of discharge (to check the reduction of maternal stress) in the checklist for each patient and finally The length of hospital stay is recorded.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Taleghani Educational and Medical Center

Full name of responsible person

Fatemeh Shahjouee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Shahjouee

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

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Name of organization / entity

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Position

Medical Student

Latest degree

A Level or less

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions will be available

Under which criteria data/document could be used

The use of data is allowed by mentioning the source

From where data/document is obtainable

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

The applicant must first register his / her request through the mentioned communication channels, and after reviewing the request for information, the information will be provided on condition of confidentiality and without identity information. This process will take a minimum of one month and a maximum of 2 months.

Comments