

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effects of Oral Motor Stimulation on the time of full oral feeding, Length of Hospital Stay, and Weight Gain in Preterm Infants(28 - 32 weeks)

Protocol summary

Study aim

Effects of Oral Motor Stimulation on the time of full oral feeding(Exclusive breast milk or formula), Length of Hospital Stay in Preterm Infants 28 - 32 weeks

Design

A randomized controlled clinical trial with parallel groups

Settings and conduct

This study is done at the Ganjavian Dezful Hospital Training Center on neonates admitted to the Neonatal Intensive Care Unit. Infants in the control group receive routine care and oral stimulation is used for infants in the intervention group during which oral massage is performed around the mouth including cheeks, lips, gums, tongue and palate. Intervention half an hour before gavage for 10 days twice a day for 15 minutes each by a speech therapy researcher. Infant was in supine position at the time of the intervention, and half an hour before the intervention, The vital signs of the baby are monitored during and half an hour after the intervention

Participants/Inclusion and exclusion criteria

Study population of preterm infants 28-32 weeks by gestational age Excluding congenital abnormalities, medial instability, and chronic medical complications such as bronchopulmonary dysplasia, grade 3 and 4 intracerebral hemorrhage, necrotizing enterocolitis, or severe sepsis

Intervention groups

Study population of preterm infants 28-32 weeks based on gestational age born in Ganjavian Hospital Training Center

Main outcome variables

Time to Independent Oral Nutrition (Exclusive Breastfeeding / Breastfeeding) and Length of hospitalization time for oral feeding. The interval between starting oral feeding and reaching independent breast feeding. The time interval between starting oral feeding and achieving independent feeding with formula. Weight at the start of oral feeding and when it comes to independent feeding with formula. Weight at discharge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191011045061N1**

Registration date: **2019-11-13, 1398/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-13, 1398/08/22**

Update count: **0**

Registration date

2019-11-13, 1398/08/22

Registrant information

Name

Hanieh Rafieiazar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3367 6703

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chesh_sabz90@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-17, 1398/07/25

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Oral Motor Stimulation on the time of full oral feeding, Length of Hospital Stay, and Weight Gain in Preterm Infants(28 – 32 weeks)

Public title

Effects of Oral Motor Stimulation on the time of full oral feeding, Length of Hospital Stay, and Weight Gain in Preterm Infants(28 – 32 weeks)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Preterm Infants in 28 – 32 weeks Studied patients have physiologic stability

Exclusion criteria:

congenital anomalies bronchopulmonary dysplasia intraventricular hemorrhage grade 3 and 4 necrotizing enterocolitis sever sepsis

Age

From 1 day old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Use RAS software for infants randomized into the control and experimental groups by using a stratified blocked randomization method Fleiss with a block size of 3 and 6

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 Dezful University of Medical Sciences

Street address

Afshar

City

Dezful

Province

Khuzestan

Postal code

64615-1147

Approval date

2019-09-03, 1398/06/12

Ethics committee reference number

IR.DUMS.REC.1398.029

Health conditions studied

1

Description of health condition studied

Effects of Oral Motor Stimulation on the time of full oral feeding, Length of Hospital Stay, and Weight Gain in Preterm Infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Time to reach full oral feeding

Timepoint

Counting the number of infant feeding daily from the beginning of the study

Method of measurement

Infant has 8 times a day for 2 consecutive days of oral breast feeding or syringe feeding

2

Description

Length of Hospital Stay

Timepoint

From the beginning of the study until the day of full oral feeding

Method of measurement

Hospitalization days count

3

Description

Weight gain

Timepoint

Weighted every other day at 24 oclock before feeding and after removing diapers and clothing

Method of measurement

Digital Balance (Seca 334, Mobile digital baby scale, CE 0123)

Secondary outcomes

1

Description

The interval between starting oral feeding and achieving full oral feeding

Timepoint

From the start of oral feeding to the day of full oral nutrition

Method of measurement

Counting the days from the start of oral feeding to the day of full oral feeding

2

Description

Time to start oral feeding

Timepoint

From the beginning of the study to the day of oral feeding

Method of measurement

Counting the days from the beginning of the study to oral nutrition

3

Description

Weight at the start of oral feeding

Timepoint

oral feeding day

Method of measurement

Digital Balance (Seca 334, Mobile digital baby scale, CE 0123)

4

Description

Weight at discharge

Timepoint

Weight measurement on discharge day

Method of measurement

Digital Balance (Seca 334, Mobile digital baby scale, CE 0123)

Intervention groups

1

Description

Intervention group: Fucile oral stimulation is used for infants in the intervention group. During which oral massage is performed around the mouth including cheeks, lips, gums, tongue and palate. Intervention is done by a speech therapist half an hour before gavage for 10 days twice a day for 15 minutes

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Ganjavian Hospital

Full name of responsible person

Shiva Bashirnejad

Street address

Afshar Street, Fatima Al-Zahra Dormitory

City

Dezful

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Khouzestan

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6461665145

Phone

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chesh_sabz90@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dezfoul University of Medical Sciences

Full name of responsible person

Maysam Mardsoltani

Street address

Afshar Street, Fatima Al-Zahra Dormitory

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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

Dezfoul 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

Dezfoul University of Medical Sciences

Full name of responsible person

Shiva Bashirnejad

Position

Academic staff of Dezful University of Medical Sciences

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Shiva Bashirnejad

Position

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Not applicable

Title and more details about the data/document

Effects of Oral Motor Stimulation on the time of full oral feeding, Length of Hospital Stay, and Weight Gain in Preterm Infants(28 - 32 weeks) in NICU Ganjavian Hospital

When the data will become available and for how long

2020/09/20 to 2021/03/20

To whom data/document is available

Enthusiasts to the subject under study

Under which criteria data/document could be used

In case of obtain written consent

From where data/document is obtainable

Project Managers

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

Send a written request letter to project managers

Comments