Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 44 3367 6703

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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
Khouzestan
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 feedig
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
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Dezful
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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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Email
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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 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
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