

# 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

##### Email address

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

##### **Province**

Khouzestan

##### **Postal code**

6461665145

##### **Phone**

+98 61 4242 2046

##### **Email**

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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##### **Province**

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##### **Postal code**

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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**

Dezfoul University of Medical Sciences

**Full name of responsible person**

Shiva Bashirnejad

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Academic Staff of Dezful University of Medical Sciences

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Shiva Bashirnejad

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**Email**

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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**