

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Effects of non-nutritive sucking and feeding in preterm infants growth,that admitted to Children's Hospital and Shariati in Bandar Abbas in 2012.

#### Protocol summary

##### Summary

Some research has shown that factors such as Skin Contact between mother and newborn, sucking on a pacifier or an empty breast feeding can be affecting the infant's development. The purpose In this study we examine the effect of pacifier sucking breast empty for growth of preterm infants admitte to Children's Hospital and Shariati in Bandar Abbas in 2012. Inclusion Criteria: Informed consent of the mother, age between 32-26 weeks and birth weight less than 1500 g.Exclusion Criteria: Neonates with severe asphyxia, malformations, cranial hemorrhage grade 3 or 4 infections at the onset or during the study and very ill newborns. In this experimental study, 69 infants will be selected and divided into three groups. Group I and Group II oral stimulation by breast-received by the pacifier in the morning and afternoon for 10 minutes. In the third group, who were selected as the control group, received no intervention. The growth parameters including weight, head circumference, weekly and daily until discharge is measured and recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013120815458N2**

Registration date: **2014-01-03, 1392/10/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-01-03, 1392/10/13

##### Registrant information

Name

Rakhshane Goodarzi

##### Name of organization / entity

Hormozgan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 1666 6242

##### Email address

rgoodarzi@oldhums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Hormozgan University of Medical Sciences

##### Expected recruitment start date

2012-06-09, 1391/03/20

##### Expected recruitment end date

2013-03-05, 1391/12/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of non-nutritive sucking and feeding in preterm infants growth,that admitted to Children's Hospital and Shariati in Bandar Abbas in 2012.

##### Public title

The effect of sucking in preterm infants without give milk that admitted to hospital

##### Purpose

Diagnostic

##### Inclusion/Exclusion criteria

Inclusion Criteria: Informed consent of the mother, age between 32-26 weeks and birth weight less than 1500 g.  
Exclusion Criteria: Neonates with severe asphyxia,

malformations, cranial hemorrhage grade 3 or 4 infections at the onset or during the study and very ill newborns

#### **Age**

To **1 year** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **69**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Hormozgan University of Medical Sciences

###### **Street address**

Shahid Chamran Blvd., beside the Governor

###### **City**

Bandarabbas

###### **Postal code**

##### **Approval date**

2013-08-12, 1392/05/21

##### **Ethics committee reference number**

HEC-92-5-21-2

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Development of feeding in preterm infants

##### **ICD-10 code**

P05-P08

##### **ICD-10 code description**

Disorders related to length of gestation and fetal growth

### **Primary outcomes**

#### **1**

##### **Description**

Amount of weight infants

##### **Timepoint**

Daily after feeding the infant

##### **Method of measurement**

Rasa microbalance

#### **2**

##### **Description**

Head circumference

##### **Timepoint**

Weekly

##### **Method of measurement**

Centimeter

### **Secondary outcomes**

#### **1**

##### **Description**

Duration of hospitalization

##### **Timepoint**

Admission until discharge

##### **Method of measurement**

daily

### **Intervention groups**

#### **1**

##### **Description**

In interventional group: neonates stimulate every day, 2 times for 15 minutes for 10 days and the breastfeeding will be done free from milk or a pacifier. Until the start of oral feeding in preterm infants. Oral intake begin when neonates stable clinically and hemodynamically. Depending on the Physical conditions, oral feeding newborn will be done 20 ml per kilogram per day. Weight and head circumference will be measured at baseline. Then weekly head circumference and weight will be measured daily. Also at the time of discharge, head circumference, and weight will be recorded. Weight recorded by one person and used directly in the microbalance RASA will be done. Weight and head circumference will be analyzed.

##### **Category**

Diagnosis

#### **2**

##### **Description**

In control group: neonates will not stimulate with the breastfeeding or pacifier. Oral intake begin when neonates stable clinically and hemodynamically. Depending on the Physical conditions, oral feeding newborn will be done 20 ml per kilogram per day. Weight and head circumference will be measured at baseline. Then weekly head circumference and weight will be measured daily. Also at the time of discharge, head circumference, and weight will be recorded. Weight

recorded by one person and used directly in the micro-balance RASA will be done. Weight and head circumference will be analyzed.

**Category**

Diagnosis

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shariati hospital

**Full name of responsible person**

**Street address**

**City**

Bandar Abbas

**2**

**Recruitment center**

**Name of recruitment center**

Children's Hospital

**Full name of responsible person**

**Street address**

**City**

Bandar Abbas

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Hormozgan University of Medical Sciences

**Full name of responsible person**

Doctor Rakhshaneh Goodarzi

**Street address**

Golshahr, Children's Hospital of Bandar Abbas

**City**

Bandar Abbas

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hormozgan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Hormozgan University of Medical Sciences

**Full name of responsible person**

Dr Rakhshaneh goodarzi

**Position**

Neonatologist, Academic staff

**Other areas of specialty/work**

**Street address**

Children's Hospital of Bandar Abbas,Golshahr

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+7 616676291

**Fax**

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Rgoodarzi@oldhums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

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Hormozgan University of Medical Sciences

**Full name of responsible person**

Dr Rakhshaneh goodarzi

**Position**

Neonatologist, Academic staff

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Hormozgan University of Medical Sciences

**Full name of responsible person**

Dr Rakhshaneh goodarzi

**Position**

Neonatologist, Academic staff

**Other areas of specialty/work**

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**Email**

Rgoodarzi@oldhums.ac.ir

**Web page address**

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*