

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### The effect of non-nutritive sucking by mother's finger on feeding tolerance and attainment of independent oral feeding of preterm infants hospitalized to the neonatal intensive care unit: a Randomized Clinical Trial Study

#### Protocol summary

##### Study aim

Determine of the effect of non-nutritive sucking by mother's finger on feeding tolerance and attainment of independent oral feeding of preterm infants hospitalized to the neonatal intensive care unit

##### Design

A clinical trial randomized with a control group, with parallel groups, single blind

##### Settings and conduct

In this clinical trial, 36 preterm infants with a fetal age of 26-34 weeks admitted to the neonatal intensive care unit of Imam Reza Hospital of Kermanshah are examined. In the intervention group, 5 minutes before the infant was fed with a feeding tube, the mother placed her little finger in the infant's mouth and stimulate the infant's sucking reflex and continues for 5 minutes after gavage. This procedure will continue twice daily for 10 days.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age 26 to 34 weeks, physiological stability with the opinion of neonatal physician. Exclusion criteria: asphyxia at birth, heart problems and serious congenital anomalies, use of narcotic drugs, congenital malformation and abnormalities in the jaw and mouth

##### Intervention groups

Intervention group: for infants in this group, non-nutritive sucking begins 5 minutes before the start of the gavage and continues for 5 minutes after it. This procedure will continue twice daily for 10 days. Control group: The neonates of this group will routinely receive the gavage, but will not receive non-nutritive sucking on the mother's finger.

##### Main outcome variables

Volume of residual milk in 1 and 2 hours after feeding, the time to start independent oral nutrition

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20151220025619N4**

Registration date: **2018-04-08, 1397/01/19**

Registration timing: **prospective**

Last update: **2018-04-08, 1397/01/19**

Update count: **0**

##### Registration date

2018-04-08, 1397/01/19

##### Registrant information

##### Name

Leila Mohammadi Pirkashani

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3835 7294

##### Email address

mohammadi.p@nm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-21, 1397/02/01

##### Expected recruitment end date

2018-06-22, 1397/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The effect of non-nutritive sucking by mother's finger on feeding tolerance and attainment of independent oral feeding of preterm infants hospitalized to the neonatal intensive care unit: a Randomized Clinical Trial Study

## Public title

The effect of non-nutritive sucking by mother's finger on feeding tolerance and attainment of independent oral feeding of preterm infants hospitalized to the neonatal intensive care unit: a Randomized Clinical Trial Study

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

gestational age 26-34 week Physiological stability with the opinion of neonatal physician

### Exclusion criteria:

Asphyxia at birth Heart problems and serious congenital anomalies Use hypnotic drugs Congenital malformation and abnormalities in the jaw and mouth

## Age

From **1 day** old to **28 days** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Care provider

## Sample size

Target sample size: **36**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The newborns are randomly divided into two random groups( intervention and control) using random numbers.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Information about the weight and age of the infants at the start of oral nutrition and the implications of the study include gastric residual volume at 1 and 2 hours after feeding, and the time to achieve independent oral nutrition for each infant in the checklist by the researcher's assistance daily. The sheet for feeding babies is reviewed and recorded. Since this person is not aware of the type of infant group, the study is done as a single blind.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Imam Reza Kermanshah Hospital., Parastar Blvd

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715838316

#### Approval date

2018-02-28, 1396/12/09

#### Ethics committee reference number

IR.KUMS.REC.1396.693

## Health conditions studied

### 1

#### Description of health condition studied

preterm infant

#### ICD-10 code

p07.3

#### ICD-10 code description

Preterm [premature] newborn [other]

## Primary outcomes

### 1

#### Description

Residual milk volume

#### Timepoint

1 and 2 hours after feeding

#### Method of measurement

By use of syringe

### 2

#### Description

Attainment of independent oral feeding

#### Timepoint

Every day until attainment of independent oral feeding

#### Method of measurement

View and register

## Secondary outcomes

### 1

#### Description

Length of hospitalization

#### Timepoint

Determine by the number of hospital days

#### Method of measurement

Count the number of hospital days

## 2

### **Description**

Weight of discharge time

### **Timepoint**

Weight of the infants is measured in time of discharge

### **Method of measurement**

By digital scale

## **Intervention groups**

### 1

#### **Description**

Intervention group: In the intervention group, 5 minutes before the infant was fed with a feeding tube, the mother placed her little finger in the infant's mouth and by moving a finger in the infant's mouth, it stimulated the infant's sucking reflex. Then the sucking started and the feeding continued in the first 5 minutes and at the same time, the infant was fed through a feeding tube. The intervention period was 10 consecutive days, and the intervention was performed twice a day.

#### **Category**

Other

### 2

#### **Description**

Control group: In the control group, infants receive routine feeding and care.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza Kermanshah Hospital

##### **Full name of responsible person**

Leila Mohammadi Pirkashani

##### **Street address**

Imam Reza Kermanshah Hospital., Parastar Blvd

##### **City**

Kermanshah

##### **Province**

Kermanshah

##### **Postal code**

6715838316

##### **Phone**

+98 83 3835 7294

##### **Email**

mohammadi1607@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Deputy of Research of Kermanshah University of Medical Sciences

##### **Full name of responsible person**

Dr Farid Najafi

##### **Street address**

Imam Reza Kermanshah Hospital., Parasar Blvd

##### **City**

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mohammadi1607@gmail.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Deputy of Research of Kermanshah 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**

Kermanshah University of Medical Sciences

##### **Full name of responsible person**

Leila Mohammadi Pirkashani

##### **Position**

Master of Science in Neonatal Intensive Care Nursing

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Nursery

##### **Street address**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available