

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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

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Email address

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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

AgeFrom **1 day** old to **28 days** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Care provider

Sample sizeTarget 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

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Imam Reza Kermanshah Hospital., Parastar Blvd

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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., Parasarar Blvd

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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

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

Kermanshah University of Medical Sciences

Full name of responsible person

Leila Mohammadi Pirkashani

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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)**

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