Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the efficacy of combination (oral sensory-motor stimulation, nonnutritive sucking and oral support) versus nonnutritive sucking on feeding performance in premature infants

Protocol summary

Study aim

To determine the effect of oral sensory-motor stimulation, non-nutritive sucking and oral support compared to non-nutritive sucking on feeding performance of premature infants.

Design

In this study, 44 preterm and premature infants who are referred to hospitals affiliated to Iran University of Medical Sciences are selected. Participants are randomly divided into intervention and control groups.

Settings and conduct

Premature infants admitted to the neonatal intensive care unit are treated in two different intervention groups for 14 consecutive days. This research has 7 stages of evaluation: before treatment, seventh day, fourteenth day, seventeenth day, twentieth day, twenty third day, final evaluation stage: The day that the infant has reached independent oral feeding. The assessment is performed using the "Preterm infant Oral Feeding Readiness Assessment Scale". Both treatment methods are performed by the investigator and all stages of the assessment by an individual other than the investigator who is blind to the treatments provided.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: modified fetal age of less than 36 weeks; no disability of oral feeding. Exclusion criteria: respiratory, cardiovascular, digestive and neurological problems or congenital syndromes.

Intervention groups

In the combined treatment group, newborns are stimulated by sensory motor stimulation for 12 minutes and 3 minutes of non-nutritive sucking with a pacifier, and receive oral milk with a glass of milk twice a day. Infants in the non-nutritive group are stimulated with a pacifier for about 5 minutes at 7-8 times.

Main outcome variables

Score of Preterm infant Oral Feeding Readiness Assessment Scale; Infant weighting; Volume of milk intake per day; Duration of full oral feeding; Duration of hospitalization.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171023036956N2**
Registration date: **2018-04-23, 1397/02/03**
Registration timing: **prospective**

Last update: **2018-04-23, 1397/02/03**
Update count: **0**

Registration date

2018-04-23, 1397/02/03

Registrant information

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Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Iran University of Medical Sciences

Expected recruitment start date

2018-04-25, 1397/02/05

Expected recruitment end date

2018-06-26, 1397/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of combination (oral sensory-motor stimulation, nonnutritive sucking and oral support) versus nonnutritive sucking on feeding performance in premature infants

Public title

The effect of combination therapy on feeding performance in premature infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

An infant with a corrected gestational age of less than 36 weeks The infant's weight is proportionate to the gestational age Apgar score equal to or greater than 3 in 1 minute and equal to or greater than 5 in 5 minutes The infant does not have the ability for oral feeding

Exclusion criteria:

Family unwillingness to continue treatment The infant has facial abnormalities The infant has respiratory, cardiovascular, digestive and neurological problems or congenital syndromes Infants with chronic medical conditions during NICU hospitalization, such as intraventricular hemorrhage and pulmonary dysplasia

Age

To **6 months** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Each premature infant with inclusion criteria will be introduced into the study group by simple random sampling. In the second step, allocation of samples will be done by random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

In the present study, both therapy methods are performed by the researcher and all stages of the assessment by an individual other than the researcher, who is blind to the intervention process.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat highway

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9411360007

Health conditions studied

1

Description of health condition studied

difficulties in oral feeding of premature infants

ICD-10 code

R63.3

ICD-10 code description

Feeding difficulties

Primary outcomes

1

Description

score of Preterm Infant Oral Feeding Readiness Assessment Scale

Timepoint

The first stage: Before the treatment, the second stage: the seventh day, the third stage: the day of the fourteenth, the fourth stage: the seventeenth day, the fifth stage: the twentieth day, the sixth stage: the twenty-third day, the final assessment stage: the day the infant is given an independent oral feeding.

Method of measurement

Preterm Infant Oral Feeding Readiness Assessment Scale(Score between 0 and 36)

Secondary outcomes

1

Description

infant weight

Timepoint
The first stage: Before the treatment, the second stage: the seventh day, the third stage: the day of the fourteenth, the fourth stage: the seventeenth day, the fifth stage: the twentieth day, the sixth stage: the twenty-third day, the final assessment stage: the day the infant is given an independent oral feeding.
Method of measurement
Scales (gr)

2

Description
The amount of milk received
Timepoint
Daily
Method of measurement
Syringe (ml)

3

Description
Duration of full oral feeding
Timepoint
The first stage: Before the treatment, the second stage: the seventh day, the third stage: the day of the fourteenth, the fourth stage: the seventeenth day, the fifth stage: the twentieth day, the sixth stage: the twenty-third day, the final assessment stage: the day the infant is given an independent oral feeding.
Method of measurement
Number of days

4

Description
Duration of hospitalization
Timepoint
Daily
Method of measurement
Number of days

Intervention groups

1

Description
Intervention Group (Combinational therapy) : Infants in the combined treatment group are stimulated oral sensory stimuli for 12 minutes and 3 minutes with a pacifier, and are stimulated twice a day with an oral support technique .
Category
Rehabilitation

2

Description
Control Group (Non-nutritive sucking) : Infants in the non-nutritive sucking group are stimulated with a pacifier 7-8 times a day for 5 minutes.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
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3

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Sponsors / Funding sources

1

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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
Iran 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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable