

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

Name

Alireza Alidad

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4438 3685

Email address

alidad.a@tak.iums.ac.ir

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

City

Tehran

Province

Tehran

Postal code

۱۳۳۹۶۱۴۵۳۵

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

Dr Farhad Zamani

Street address

Firoozgar Hospital, Beh Afarin St., Karim Khan St., Vali-e-Asr Square

City

Tehran

Province

Tehran

Postal code

۱۵۹۳۷۴۷۸۱۱

Phone

+98 21 8894 0489

Fax

+98 21 8894 2622

Email

h_firoozgar@yahoo.com

2

Recruitment center

Name of recruitment center

Rasul-e Akram Hospital

Full name of responsible person

Ali Kabir

Street address

Rasul-e Akram Hospital, Mansouri St , Sattarkhan St.

City

Tehran

Province

Tehran

Postal code

۱۴۴۵۶۱۳۱۳۱

Phone

+98 21 6651 5000

Fax

+98 21 8805 2248

Email

PR@iums.ac.ir

3

Recruitment center

Name of recruitment center

Aliasghar Children's hospital

Full name of responsible person

Nakisa Hooman

Street address

Aliasghar Children's hospital, Dastgerdi st , Modarres hwy

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2222 2041

Fax

+98 21 8805 2248

Email

aach@iums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Ali Javad Mousavi

Street address

Iran University of Medical Sciences, Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8862 2553

Fax

+98 21 8862 2703

Email

Dr_moosavi@yahoo.com

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**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mr Alireza Alidad

Position

Master of science/ researcher

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

Street address

School of Rehabilitation Sciences Speech & Language Pathology department, Shahnazari St, Mirdamad Blv.

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 982122227124

Fax

+98 21 2222 0946

Email

alireza.alidad@gmail.com

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

Iran University of Medical Sciences

Full name of responsible person

Dr Leila Ghelichi

Position

Assistant professor/PhD of Speech Therapy

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

Street address

School of Rehabilitation Sciences Speech & Language Pathology department, Shahnazari St, Mirdamad Blv.

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 8051

Fax

+98 21 2222 0946

Email

ghelichi.i@iums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mr Alireza Alidad

Position

Student of MSc. of Speech therapy

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

Street address

School of Rehabilitation Sciences Speech & Language
Pathology department, Shahnazari St, Mirdamad Blv.

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 7124

Fax

+98 21 2222 0946

Email

alireza.alidad@gmail.com

Web page address

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