

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The Effect of the combination of Kinesio-taping and Oral Motor Intervention on feeding functions of Premature Infants with Feeding Difficulties Hospitalized in the NICU

Protocol summary

Study aim

Examine the effects of oral stimulation combined with Kinsiotape on feeding efficiency for Premature Infants admitted to the NICU

Design

The clinical trial consisted of a control group with parallel groups, single blind, randomized, and a sample size of 45 preterm infants.

Settings and conduct

This study is a single-blind randomized clinical trial in which the evaluators will be unaware of the type of intervention that each infant will receive. This study will be carried out after receiving permission to conduct research from the Iran University of Medical Sciences in the neonatal intensive care unit of Akbarabadi Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Premature Infants The inclusion criteria: gestational age between 30-34 weeks physiological stability during taping and oral stimulations Apgar score equal or more than 5 at 5 minutes after birth birth weight between 1000 and 1500g not receiving mechanical ventilation no severe or chronic medical status or congenital anomalies. The exclusion criteria: premature infants who were transferred to other hospital or centers physiological instability during oral intervention and taping show skin allergies or other allergies using KT.

Intervention groups

Group 1: Premature Infant Oromotor Intervention Combined with Kinsiotape Group 2: Premature Infant Oromotor Intervention Group 3: Kinsiotape and routine nursing program

Main outcome variables

Premature Oral Feeding Readiness Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210905052381N1**

Registration date: **2021-09-20, 1400/06/29**

Registration timing: **prospective**

Last update: **2021-09-20, 1400/06/29**

Update count: **0**

Registration date

2021-09-20, 1400/06/29

Registrant information

Name

Ehsan Naderifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4252 4658

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2021-11-22, 1400/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of the combination of Kinesio-taping and Oral Motor Intervention on feeding functions of Premature Infants with Feeding Difficulties Hospitalized in the NICU

Public title

Nutritive Sucking in Premature Infants

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

APGAR score above 5 for 5 min Absence of congenital anomalies (such as heart, mouth, etc.) or severe medical problems Gestational age between 30-34 weeks weight at birth between 1000-1500g Tube feeding

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: 45

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, random allocation will be done by a person who is not present in the the investigation process and does not know the groups. it will be done using the Random allocation rule. In this method, after determining the total sample size, a set of them is randomly assigned to each group and for the number of samples in each group, in the sheets, the name of the treatment group will be written briefly. The sheets will be placed in opaque envelopes and all will be placed in the container. The person who is not involved in any of the research steps will then be asked to randomly choice the envelopes and the sequence created will be recorded. Then, according to the sequence created for infants with inclusion criteria, treatment will be used.

Blinding (investigator's opinion)

Single blinded

Blinding description

The staff of the department will not be aware of the treatment used. Also, the assessor (speech and language pathologist), who is someone other than the therapist, will not know about the treatment groups because the assessments will be done after the separation of the type.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Iran University of Medical Sciences

Street address

Shahid Hemmat Highway between Sheikh Fazl ...
Nouri and Shahid Chamran, Iran University of Medical Sciences

City

Tehran

Province

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Postal code

1449614535

Approval date

2021-08-29, 1400/06/07

Ethics committee reference number

IR.IUMS.REC.1400.479

Health conditions studied**1****Description of health condition studied**

Oral feeding disorders in premature infants

ICD-10 code

R13.19

ICD-10 code description

Other dysphagia

Primary outcomes**1****Description**

Premature Oral Feeding Readiness Scale

Timepoint

First, fourth and seventh days of intervention

Method of measurement

Premature Oral Feeding Readiness Scale

Secondary outcomes**1****Description**

Mean Volume Intake

Timepoint

First, fourth and seventh days of intervention

Method of measurement

% volume intake in 5 minutes divided by the prescribed volume

2

Description

Weight gain

Timepoint

First, fourth and seventh days of intervention

Method of measurement

Put the baby on a digital balance and record the baby's weight to gram

3

Description

Improvement interval of oral intake.

Timepoint

First, fourth and seventh days of intervention

Method of measurement

the MV from Day 1 (the baseline) will subtracted from the MV of Days 4 or 7, then will divided by the baseline

4

Description

Duration of the hospitalization

Timepoint

First, fourth and seventh days of intervention

Method of measurement

Interval between the first day of preterm infant referral to the NICU until the last day (discharge)

Intervention groups

1

Description

Intervention group: Present PIOMI intervention before feeding and for 5 minutes a day for seven consecutive days and then use the kinesiotape of orbicularis oris muscle, mylohyoid-sternohyoid and masseter muscle for 7 consecutive days and daily change of them.

Category

Rehabilitation

2

Description

Intervention group: Present PIOMI intervention before feeding and for 5 minutes a day for seven consecutive days

Category

Rehabilitation

3

Description

Control group: use the kinesiotape of orbicularis oris muscle, mylohyoid-sternohyoid and masseter muscle for 7 consecutive days and daily change of them and routine nursing care

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbar Abadi Hospital

Full name of responsible person

Ehsan Naderifar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Iran University of Medical Sciences

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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

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ehsan Naderifar

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Speech therapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Leila Ghelichi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

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

Analytic Code

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

Data Dictionary

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