Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 than5 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)

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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
Tehran
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
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Shahid Hemmat Highway between Sheikh Fazl ... Nouri and Shahid Chamran, 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

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Person responsible for updating data

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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