

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effectiveness of Kinesiotaping on Nutritive Sucking in Premature Infants Admitted to the NICU

Protocol summary

Study aim

Comparison Effects of Kinesiotape and oral stimulation program on Nutritive Sucking in Premature Infants Admitted to the NICU

Design

The controlled clinical trials, based on the individual, with parallel groups, double-blind, randomized and the sample size is 10 premature infants.

Settings and conduct

This study is a double-blind randomized clinical trial because the evaluator will be unaware of the effects of the type of intervention that each baby will receive. This study will be carried out from the Deputy Chancellery of Ahvaz Jundishpour University of Medical Sciences in the neonatal intensive care unit of Emam Khomeini Hospital in 2019-2020 after obtaining a license.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Premature infants with Gestational age between 28 and 34 weeks, Weight of birth between 1000 and 2000 grams, Receiving all feedings through a tube, Stable physiologic signs at the onset of feeding stimulation, Exclusion criteria: present of congenital anomalies (such as cardiac, oral, etc.) or severe medical complications or severe problems such as bronchopulmonary dysplasia, grade III or IV intraventricular hemorrhage, necrotizing enterocolitis, present of neuropathy, present of genetic syndromes, present of asphyxia, present of sepsis, present of congenital craniofacial malformations, present of respiratory disease.

Intervention groups

One group receive oral stimulation program and another group receive Kinesiotape concomitant with oral stimulation program. The duration of the intervention is 10 days for both groups.

Main outcome variables

Feeding Progression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190515043599N1**

Registration date: **2019-07-18, 1398/04/27**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-18, 1398/04/27**

Update count: **0**

Registration date

2019-07-18, 1398/04/27

Registrant information

Name

Azadeh Abedinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3101

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-24, 1398/03/03

Expected recruitment end date

2019-09-25, 1398/07/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Kinesiotaping on Nutritive Sucking in Premature Infants Admitted to the NICU

Public title

Nutritive Sucking in Premature Infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age between 28 and 34 weeks Weight of birth between 1000 and 2000 grams Receiving all feedings through a tube Stable physiologic signs at the onset of feeding stimulation

Exclusion criteria:

present of asphyxia present of sepsis present of respiratory disease present of congenital anomalies (such as cardiac, oral, etc.) or severe medical complications or severe problems such as bronchopulmonary dysplasia, grade III or IV intraventricular hemorrhage, necrotizing enterocolitis present of neuropathy present of genetic syndromes present of congenital gastrointestinal malformations

Age

From **1 day** old to **20 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Randomized

Randomization description

Given that the homogeneity of the studied groups is important in terms of gender and age, the covariate adaptive randomization method will be used. The first participant will be randomly assigned to one of the intervention or control groups and the next participant will be assigned to a group that has a lower age and gender attribute, respectively. Randomization will be done by Minim software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both parents of participants and outcome evaluator are unaware of the allocation of study groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan St

City

Ahvaz

Province

Khouzestan

Postal code

15794-61357

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.AJUMS.REC.1398.147

Health conditions studied

1

Description of health condition studied

Dysphagia in premature infants

ICD-10 code

R13.19

ICD-10 code description

Other dysphagia

Primary outcomes

1

Description

Feeding Progression

Timepoint

during intervention

Method of measurement

Record of the number of days since the onset of oral feeding until the achievement of independent oral feeding

Secondary outcomes

1

Description

Weight gain

Timepoint

before intervention and Immediately after the end of the intervention

Method of measurement

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

2

Description

Feeding proficiency

Timepoint

since the onset of oral feeding until the achievement of

independent oral feeding
Method of measurement
% ml taken during the first 5 min/ml prescribed

3

Description

Sucking frequency

Timepoint

since the onset of oral feeding until the achievement of independent oral feeding

Method of measurement

number of sucking per minutes

4

Description

Feeding duration time

Timepoint

since the onset of oral feeding until the achievement of independent oral feeding

Method of measurement

All periods in which the infant had the nipple inside the mouth

Intervention groups

1

Description

Intervention group: Receiving Kinesiotape concomitant with oral stimulation program

Category

Rehabilitation

2

Description

Control group: Receiving oral stimulation program

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Azadeh Abedinzadeh

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Azadegan Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badvi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Negin Moradi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Speech therapy

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Person responsible for scientific inquiries

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Azadeh Abedinzadeh

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

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Person responsible for updating data

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Latest degree

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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