

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of oral massage on independent sucking time in premature infants

Protocol summary

Study aim

The effect of oral massage on the time of acquisition independent sucking in preterm infants

Design

Clinical trial with control group

Settings and conduct

This study is carried out at the rehabilitation center of Birjand University of Medical Sciences. Participating infants fall into two groups. One group receives a Beckmann massage program and the other group receives similar movements. In fact, the second group does not receive intervention and their parents do not know about it. Then, the time to acquisition independent sucking are counted with the condition of 10 times independent sucking and feeding per day, from the beginning of the study.

Participants/Inclusion and exclusion criteria

Premature infants of 28 to 32 weeks of age with no respiratory problems, cleft palate and other facial anomalies who have stable vital condition and continue to receive intubation for at least one month after birth.

Intervention groups

Babies fall into two groups. One group receives a Beckmann massage program and the other group receives similar massage like movements

Main outcome variables

Possible changes may include decreasing intubation time, accelerating the acquisition of independent sucking time in neonates, increasing neonatal weight gain, as well as increasing coordination of swallowing and breathing and muscle strength during sucking.

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20200105046018N1**

Registration date: **2020-01-14, 1398/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-14, 1398/10/24**

Update count: **0**

Registration date

2020-01-14, 1398/10/24

Registrant information

Name

Elahe Farmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3238 1400

Email address

elahe.farmani@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral massage on independent sucking time in premature infants

Public title

sucking in preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Disability in independent sucking and feeding through intubation for at least one month after birth تولد با سن جنینی بین 28 تا 32 هفته

Exclusion criteria:
The presence of oral maxillary anomalies and cleft palate
Respiratory problems and unstable vital conditions

Age
From **15 days** old to **180 days** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
Infants fall into two groups. The Beckmann program massage is performed for one group and the control group observes similar movements to their infant. In fact, this group does not receive sensory motor stimulation and is intended to prevent the mother from imitating.

Placebo
Used

Assignment
Other

Other design features
Babies fall into two groups. One group receives a Beckmann massage program and the other group receives massage-like movements.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Ghafari street

City

Birjand

Province

South Khorasan

Postal code

9۷۱۷۸۵۳۵۷۷

Approval date

2019-10-14, 1398/07/22

Ethics committee reference number

22/07/1398

Health conditions studied

1

Description of health condition studied

sucking in preterm infants

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

time of acquisition independent sucking

Timepoint

Once a week, one week from the start of the program

Method of measurement

Ability to suck ten times independently of mother's breast or glass

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group of infants receive a Beckmann massage program once a day in the rehabilitation clinic setting and twice at home by the mother.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

clinic of rehabilitation Birjand University of medical science (Hakim)

Full name of responsible person

Elahe Farmani

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elahe.farmani@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Ebrahim Miri

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ghafari st

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9717853577

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Fax

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Email

research@bums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Elahe Farmani

Position

instructor of speech and language pathology

Latest degree

Master

Other areas of specialty/work

Speech therapy

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Part of the data, such as information on when to suck, can be shared

When the data will become available and for how long

from 03/2020

To whom data/document is available

Researchers working in universities and rehabilitation centers

Under which criteria data/document could be used

Feel free to carry out similar or complementary studies

From where data/document is obtainable

Email: elahe.farmani@bums.ac.ir

What processes are involved for a request to access data/document

Information will be transmitted within 15 days after receiving the email.

Comments