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

۹۷۱۷۸۵۳۵۷۷

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

Street address

Shahed 1. corner of sardaran shahid

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۵۷۷

Phone

+98 56 3241 1671
Email
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
Street address
ghafari st
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1400
Fax
+98 56 3238 1200
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
Street address
Ghafari st. Birjand University of medical science
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1400
Email
elahe.farmani@bums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Elahe Farmani
Position
instructor of speech therapy
Latest degree
Master
Other areas of specialty/work
Speech therapy
Street address
Ghafari st
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1400
Email
elahe.farmani@bums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Elahe Farmani
Position
instructor of speech therapy
Latest degree
Master
Other areas of specialty/work
Speech therapy
Street address
Ghafari st
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1400
Email
elahe.farmani@bums.ac.ir

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