Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Investigating the effect of Premature infant oral motor intervention and fossil treatment approaches in term infants with inpatient swallowing disorder in neonatal intensive care unit: A clinical trial study

Protocol summary

Study aim

Evaluation of the effect of fossil and PIOMI treatment approaches in term neonates with swallowing disorder admitted to NICU: A clinical trial study

Design

The treatment sessions of each group will include 7 to 10 sessions according to the main protocol. Before and after treatment, infants' sucking skills will be assessed by their pediatrician, discharge time and fullfeeding, and the baby's swallowing status will be assessed by a speech and language specialist using the NFAS screening test.

Settings and conduct

Each method will be performed according to the main protocol table of approaches in the neonatal intensive care unit of Ghaem Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Infants longer than and equal to 37 weeks of gestation admitted to the NICU of Ghaem Hospital 2. Newborns who have difficulty swallowing and sucking for any reason related to their underlying disease (such as asphyxia, metabolic diseases, brain disorders, infections, etc.). 3. The parents of these babies want their child to participate in the study. 4. Have a swallowing disorder according to the NFAS screening test. Exclusion criteria: 1. If parents do not want to 2. In case of progressive disease 3. In case of risk of unmanageable injury to the baby 4. Presence of congenital anomalies (cleft lip and palate) 5. Infants with chromosomal abnormalities

Intervention groups

. Samples will include full-term neonates with dysphagia randomly assigned using a random number table in three groups of 17 people.Protocol "A" will include PIOMI treatment and protocol "B" will include fossil drills. The first group will receive "A" protocol, the second group will receive "B" protocol and the control group will receive group C routine treatment.

Main outcome variables

Infant weight, hospitalization time and Fullfeeding status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201221049790N1**
Registration date: **2021-03-03, 1399/12/13**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-03, 1399/12/13**
Update count: **0**

Registration date

2021-03-03, 1399/12/13

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-23, 1399/10/03

Expected recruitment end date

2021-11-24, 1400/09/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Premature infant oral motor intervention and fossil treatment approaches in term infants with inpatient swallowing disorder in neonatal intensive care unit: A clinical trial study

Public title

Investigating the effect of Premature infant oral motor intervention and fossil treatment approaches in term infants with inpatient swallowing disorder in neonatal intensive care unit: A clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Newborns more than and equal to 37 weeks of gestation admitted to the NICU ward of Ghaem Hospital Term infants who have difficulty swallowing and sucking for any reason related to their underlying disease (such as: asphyxia, metabolic diseases, brain disorders, infections, etc.). The parents of these babies want their child to participate in the study. According to the NFAS screening test have swallowing disorders.

Exclusion criteria:

If parents do not want to In case of progressive disease In case of risk of unmanageable injury to the baby Presence of congenital anomalies (cleft lip and palate) Infants with chromosomal abnormalities

Age

From **1 day** old to **40 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, first, three groups of blocked blocks for treatments were considered as codes A, B and C, and according to the first type of permuted block randomization method, the number of each group was equal to 17 people. Giving to the groups) was written on paper and by removing one of the papers as the first block and the next paper as the second block and finally the remaining paper as the third block.17 The first infant hospitalized in the first block and The next 17 infants in the second block and the other 17 infants in the third block were treated according to their code.

Blinding (investigator's opinion)

Single blinded

Blinding description

The interventions of each group will take place at a specific time in a separate room in the nICU and the parents of the participants will be unaware of the assignment of the other groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical sciences

Street address

Khorasan Razavi, Mashhad, East Door Of Ferdowsi University, Public Relations Department Of The University

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Postal code

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Approval date

2020-12-23, 1399/10/03

Ethics committee reference number

IR.MUMS.REC.1399.473

Health conditions studied

1

Description of health condition studied

feeding problems that occur in full-term infants.

ICD-10 code

P92.8

ICD-10 code description

Other feeding problems of newborn

Primary outcomes

1

Description

The weight of the infants and the time of discharge from the hospital and check that the infant is fed in a normal volume and orally.

Timepoint

10 days after the intervention

Method of measurement

The weight and time of admission and the infant sucking status will be assessed by the speech therapist (researcher) using the neonatal swallowing assessment test and the infant fullfeeding status will be assessed by the neonatal specialist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In group A in the present study, according to the treatment protocol, the PIOMI approach will be standard and valid . These exercises are used to increase motor-oral skills and coordination of sucking, swallowing and breathing.Performing these exercises for about 5 minutes 3 times a day in group A will take time and these exercises will be performed in 10 consecutive and intensive days and after the exercises, they will be re-evaluated.
Category
Treatment - Other

2

Description
Intervention group: The exercises used to improve swallowing disorders in group B in the present study will be according to the treatment protocol of the fossil approach by Fucile et al., Which is standard and valid for full-term infants. Breathing is used. These exercises will take about 15 minutes in Group B and will be performed for 10 consecutive days.
Category
Treatment - Other

3

Description
Control group: Group C control group who will receive routine hospital treatment.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Davood Sobhani
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Sponsors / Funding sources

1

Sponsor
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Davood Sobhani
Position
Faculty Member And Director Of Speech Therapy Group
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
After reading and publishing the article, he will be allowed to request information.

When the data will become available and for how long
After printing the results

To whom data/document is available
Researchers in academic and scientific institutions

Under which criteria data/document could be used
After reading and publishing the article, he will be allowed to request information.

From where data/document is obtainable
Responsible for the project Davood Sobhani 09155041233 sobhanid@mums.ac.ir

What processes are involved for a request to access data/document
After reading and publishing the article, he will be allowed to request information.

Comments