Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of the effect of cup, syringe and finger feeding on timing of complete oral feeding and weight gain in preterm infants: a randomized controlled clinical trial

Protocol summary

Study aim

Comparison of the effect of cup, syringe and finger feeding on timing of complete oral feeding and weight gain in preterm infants

Design

Clinical trial has three intervention groups, with parallel, no blind, randomized, phase 2 groups on 99 patients. Excel software rand function was used for randomization.

Settings and conduct

The target population is premature infants 30-30 weeks hospitalized in the intensive care unit of Al-Zahra and Taleghani educational and medical centers in Tabriz. The total sample size will be 99 people and the sample size in each group will be 33 people.

Participants/Inclusion and exclusion criteria

The age of the infant at the time of sampling is 30-34 weeks with stable clinical condition Ability to swallow of newborn for two days Apgar fifth minute at birth higher than 7

Intervention groups

En Intervention group 1:The baby is kept in a sitting or semi-sitting position with head-body coordination.The edge of the cup is placed on the lower lip of the baby and the baby sucks the milk from the cup with forward movements of the tongue. En Intervention group 2: After washing the hands and wearing disposable gloves, the researcher or mother will glue the stomach tube to her little finger. By placing a finger in the baby's mouth and sucking, the milk will be transferred to the baby's mouth through the stomach tube. Intervention group 3: In this feeding method, the piston is squeezed while the premature baby is sucking and the milk is directed to the inside of the cheek.

Main outcome variables

Time to achieve complete oral nutrition; weight gain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150424021917N11**
Registration date: **2020-12-22, 1399/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-22, 1399/10/02**
Update count: **0**

Registration date

2020-12-22, 1399/10/02

Registrant information

Name

Sevil Hakimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of cup, syringe and finger feeding on timing of complete oral feeding and weight gain in preterm infants: a randomized controlled clinical trial

Public title
Effect of cup, syringe and finger feeding on timing of complete oral feeding and weight gain in preterm infants: a randomized controlled clinical trial

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
The age of the infant at the time of sampling is 30-34 weeks with stable clinical condition Ability to swallow of newborn for two days Apgar minute 5 higher than 7
Exclusion criteria:
Intra Ventricular Hemorrhage grade 3 or 4 Sepsis Newborn under CPAP or ventilator Congenital malformation Down Syndrome Neuromuscular diseases

Age
From **210 days** old to **238 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **99**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly assigned to three groups of finger feeding, cup feeding, and syringe feeding blocks with blockes size 6 and 9 ratio of 1: 1. The allocation sequence will be determined using Random Allocation Software (RAS). To allocation cocealment, the type of intervention will be written on paper and placed in sealed opaque envelopes that are numbered sequentially. The envelopes will be opened by the person not involved in the sampling.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Third Floor, Central Building of Number 2, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5138665793

Approval date
2020-11-25, 1399/09/05

Ethics committee reference number
IR.TBZMED.REC.1399.819

Health conditions studied

1

Description of health condition studied
Premature neonate

ICD-10 code
P07.33

ICD-10 code description
premature neonate, gestational age 30 completed weeks

Primary outcomes

1

Description
Time to reach complete oral nutrition

Timepoint
Before the intervention and then after the intervention

Method of measurement
Using a researcher-made questionnaire

Secondary outcomes

1

Description
The rate of weight change

Timepoint
The baby's weight will be measured at the beginning of the study and then daily at a specific time in the morning shift before feeding and then after feeding the baby daily until full oral feeding.

Method of measurement
Weight in grams with a digital scale

Intervention groups

1

Description
Intervention group 1: 33 premature infants will be

breastfed or complementary milk with a 50 ml disposable plastic cup.The baby is kept in a sitting or semi-sitting position with head-body coordination.The edge of the cup is placed on the lower lip of the baby and the baby sucks the milk from the cup with forward movements of the tongue.

Category

Other

2

Description

Intervention group 2: 33 premature infants will be fed with breast milk or complementary milk through a gavage tube attached to the mother's finger.In this method, breast milk or auxiliary milk is poured into a syringe and a gastric tube is attached to it. After washing the hands and wearing disposable gloves, the researcher or mother will glue the stomach tube to her little finger. By placing a finger in the baby's mouth and sucking, the milk will be transferred to the baby's mouth through the stomach tube.

Category

Other

3

Description

Intervention group 3: 33 premature infants will be fed breast milk or complementary milk through a syringe.In this feeding method, the piston is squeezed while the premature baby is sucking and the milk is directed to the inside of the cheek.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Sevil Hakimi
Street address
Alzahra Hospital, South Artesh St.
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2

Recruitment center

Name of recruitment center
Taleghani Educational and Medical Center, Tabriz
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology University of Medical Sciences
Full name of responsible person
Sevil Hakimi
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No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, East Azerbaijan, Iran
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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
Vice Chancellor for Research and Technology 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
Tabriz University of Medical Sciences
Full name of responsible person
Parinaz Alinazhad Shebilouy Sofla
Position
Master student of midwifery
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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South Shariati St., School of Nursing and Midwifery, Tabriz University Of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not 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
Only part of the data such as information about the main outcome or the like can be shared. The results of the clinical study will be published as an article.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific use with reference to the article
From where data/document is obtainable
sevil hakimi - hakimis@tbzmed.ac.ir
What processes are involved for a request to access data/document
The applicant notifies the applicant by email, after receiving the email the results are sent.
Comments