Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison of Cue based Feeding and Volume Based Feeding on Blood Glucose of preterm infants

Protocol summary

Study aim
Comparison of blood glucose of premature neonates in two cue based feeding and volume based feeding methods

Design
Clinical trial in two randomized parallel group, 61 infant in each group. Randomization will be done in a block random manner. RAS statistical software, block randomization tool will also be used to determine the sequence of blocks.

Settings and conduct
Mahdiyeh hospital in Tehran , NICU unit. Babies in cue based group will be fed by caregiver/mother whenever behavioral signs of hunger happen (seeking reflex, bringing hands closer, licking or sucking on the lips, etc.). They will stop feeding when symptoms related to being full (closing the mouth, decreasing muscle tone and falling asleep, unwillingness to suck, etc.) appear. If the baby in the intervention group does not show signs of hunger after 4 hours from the previous feeding, the caregiver will wake up the baby and feed the baby under the breast or with a cup or gavage. In the volume based feeding group, the caregiver will give the specified volume to the baby at specified intervals of 2 to 3 hours. Pre feeding blood glucose will be monitored every 6 hours for 3 days with a glucometer, feeding intolerance episodes and weight of the babies will be monitored daily.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Premature neonates with corrected age of 32 weeks and above; Tolerate full enteral feeding and parentral nutrition has been stopped; Parents' consent to enter the study Exclusion criteria: Need for invasive and/or non invasive mechanical ventilation; Congenital abnormalities; Gastrointestinal surgery; Intra Ventricular Hemorrhage grade 3 or more; Swallowing disorder

Intervention groups
In the intervention group, the doctor's order for feeding will be on demand. In the control group, feeding will be based on volume (usual care)

Main outcome variables
Pre feeding blood glucose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220704055362N2**
Registration date: **2023-01-21, 1401/11/01**
Registration timing: **prospective**

Last update: **2023-01-21, 1401/11/01**
Update count: **0**

Registration date
2023-01-21, 1401/11/01

Registrant information

Name
Elahe Rastkar Mehrabani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5506 2628

Email address
elaheh.rastkar86@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2024-02-20, 1402/12/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Cue based Feeding and Volume Based Feeding on Blood Glucose of preterm infants

Public title

Comparison of Cue based Feeding and Volume Based Feeding on Blood Glucose of preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Premature babies with a corrected age of 32 weeks and older Full enteral feeding has been tolerated and parentral nutrition has been discontinued Parental consent

Exclusion criteria:

Need for invasive and/or non invasive mechanical ventilation Congenital abnormalities Gastrointestinal surgery Intra Ventricular Hemorrhage grade 3 or more Swallowing disorder Lack of parental consent

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

The classification of the samples to be assigned to the treatment groups will be done in a block random manner. The randomization unit is considered individual. RAS statistical software, block randomization tool will also be used to determine the sequence of blocks. The sealed cover letter will be used for allocation concealment. We consider the capacity of the blocks as 4 and then we write all the possible permutations for this block, which are defined as follows. (1: ABAB) and (2: AABB) and (3: BBAA) and (4: BABA) and (5: ABBA) and (6: BAAB) By means of statistical software, we randomly select one of the numbers of permutations and consider the block corresponding to it. For example, if the first random selection of block 2 is selected, the first person will receive treatment A, the second person will receive treatment A, the third person will receive treatment B, and the fourth person will receive treatment B. To reach a sample size of 61 per group, we continue this sequence 30 times. After selecting all the blocks, we randomly assign indices B and A to one of the treatment groups.

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 Shahid Beheshti University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1419943471

Approval date

2023-01-01, 1401/10/11

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.652

Health conditions studied

1

Description of health condition studied

Hypoglycemia

ICD-10 code

E16.2

ICD-10 code description

Hypoglycemia, unspecified

2

Description of health condition studied

Prematurity

ICD-10 code

P07.30

ICD-10 code description

Preterm newborn, unspecified weeks of gestation

Primary outcomes

1

Description

Blood glucose

Timepoint

From the time of entry into the study for 3 days with intervals of every 6 hours

Method of measurement

Capillary blood glucose test from the heel with a

glucometer

Secondary outcomes

1

Description
Episodes of feeding intolerance
Timepoint
From the time of entering the study for 3 days, after each feeding (every 3 to 4 hours)
Method of measurement
Report of caregiver (nurse/mother) and importing in the checklist

2

Description
The rate of weight gain of neonates
Timepoint
From the time of entering the study till the day of discharge, daily assessment
Method of measurement
Weighing with a digital scale by the caregiver every morning

3

Description
The number of days the baby is hospitalized
Timepoint
From the time of entering the study till the day of discharge, one time at discharge day
Method of measurement
Calculation of the number of days of hospitalization of the baby from the time of entering the study to the day of discharge. Baby's medical record

Intervention groups

1

Description
Control group: Feeding the baby will be done based on volume (usual method). A certain amount of milk (breast milk or formula) will be given to the baby every 2 to 3 hours according to the doctor's order.
Category
Treatment - Other

2

Description
Intervention group: Feeding the baby will be done based on the baby's behavioral cues. By observing the cues related to the baby's hunger, the baby will be fed with breast milk or formula, and as soon as the behavioral cues related to fullness appear, the feeding will be stopped. The amount and intervals of feeding will be determined by the baby.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdiyeh Hospital
Full name of responsible person
Farzaneh Palizban
Street address
Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Next to Ayatollah Taleghani Hospital ,Evin , Tehran, Iran
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Province
Tehran
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Phone
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info@sbmu.ac.ir
Web page address
https://sbmu.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Elahe Rastkar Mehrabani
Position
NICU nurse
Latest degree
Master
Other areas of specialty/work
Neonatal intensive care nursing
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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
Undecided - It is not yet known if there will be a plan to make this available
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