

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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

Mahdijeh 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 parental 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 parenteral 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

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

Mahdijeh 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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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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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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Person responsible for updating data**Contact****Name of organization / entity**

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Nurse

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Subspecialist

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Neonatal-Perinatal Medicine

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City

Tehran

Province

Tehran

Postal code**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