

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of nutrition education based on neonatal behavioral symptoms of nurses on short-term health outcomes in preterm infants.

Protocol summary

Study aim

The purpose of this study was to determine the effect of nutrition education on neonatal behavioral symptoms to nurses on the short-term health outcomes of preterm infants.

Design

Clinical trial with control group without educational intervention and intervention group with educational intervention.

Settings and conduct

Neonatal of intensive care unit of Yas hospital in Tehran and train nurses.

Participants/Inclusion and exclusion criteria

The criteria for entry include preterm infants from 28 to 36 weeks of gestational age, whose intravenous feeding period is completed and intravenous fluids stopped and have an autonomic stability and for starting oral feeding should be weight above 1500g or over 34 gestational age and be inside the incubator. The exit criteria of neonates include the need for invasive respiratory protection, patients with grade 3 and 4 interaventricular hemorrhage, necrotic enterocolitis, and which after the onset of the study reduced or decreased weight gain 3 consecutive days or serum-therapy and stop of nutrition. Nurses' entry criteria including at least 6 months of work experience with the newborn, participation in the training course and the willingness to participate in project.

Intervention groups

Starting of study is with 30 infant in control groups that according to the physician's order, every two to three hours without regard to the infant's demand are fed, and information is collected in the checklist, and then hold a training course for the health care staff. Study started in two shifts of 12-hour day and night on infants is based on CBF protocols and information from each infant is entered into the checklist, thus the short-term health outcomes of the preterm infants in both groups are compared.

Main outcome variables

Short-time health outcomes of preterm infant include duration of hospitalization, weight gain, Apnea times.

General information

Reason for update

Acronym

CBF

IRCT registration information

IRCT registration number: **IRCT20170828035962N2**

Registration date: **2018-05-27, 1397/03/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-27, 1397/03/06**

Update count: **0**

Registration date

2018-05-27, 1397/03/06

Registrant information

Name

samane sefatbagha

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66713119

Email address

sefatbagha@gmail.com

Recruitment status

Recruitment complete

Funding source

Babil University of Medical Sciences, Amirkola Non-Communicable Disease Research Center

Expected recruitment start date

2017-06-26, 1396/04/05

Expected recruitment end date

2018-07-21, 1397/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of nutrition education based on neonatal behavioral symptoms of nurses on short-term health outcomes in preterm infants.

Public title
The effect of CBF on short-term health outcomes of infants

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Preterm infants from 28 to 36 weeks of pregnancy that complete intestinal feeding, and their intravenous feeding period was complete, when they could eat milk to the 120 ml / kg / day, and we can stop intravenous fluids. At this time, only infants who weigh over 1500 grams or older than 34 weeks of gestation can begin their oral feeding, or the physiological stability of the autonomic system (skin color, heart rate and respiration) The infants should be transferred to incubator and be sure to monitor the heart. The inclusion criteria of the nurses in the study include: having at least 6 months work experience in neonatal intensive care units, participating in the curriculum score and willingness of nurses to participate in the project,
Exclusion criteria:
 Premature infants requiring respiratory support by invasive and non-invasive mechanical ventilation (but oxygen therapy with other methods such as oxy hood, canola and free oxygen at the incubator level, interfering with our intervention) Infant with interaventricular hemorrhage grade 3 and 4 Infant with necrozan enterocolitis Infant with Broncho Pulmonary Dysplasia Infant with Congenital disorder Infant with Surgical Disorder Infant with sepsis Infants who receive sedative and sedative drugs such as phenobarbital, midazolam, fentanyl, or morphine Infants who lose weight or lack of weight gain for 3 consecutive days after the start of the study. Infant with mothers are addicted to alcohol or narcotics Do any other supportive interventions, such as therapeutic touch and music therapy during the study. The criteria for leaving nurses are reluctance to participate in the plan

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Short-term health outcomes include the duration of infant access to oral nutrition, duration of hospitalization, weight gain, apnea and O2Sat loss rates.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Gangafrroz Ave., Babol, Mazandaran.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2017-06-25, 1396/04/04

Ethics committee reference number

MUBABOL.HRI.REC.1396.4

Health conditions studied

1

Description of health condition studied

Infant feeding of Cue Based : CBF

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Neonate weight gain

Timepoint

At the beginning of the shift in morning

Method of measurement

In gram by using digital scale

Secondary outcomes

empty

Intervention groups

1

Description

To begin the study, at first, the control group samples were evaluated with a sample size of 30 neonates. The group was routinely administered on an hourly basis (every two hours or three hours), regardless of the demand of the baby and with any nutrition

Category

Behavior

2

Description

After taking samples in the control group, they began organizing workshops, distributing educational pamphlets, and installing nutrition protocols on request based on posters. The teaching materials for nurses in the workshops were: Definition of NIDCAP a

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Samane Sefatbaqa

Street address

side of Sarv St.Ostad Nejatollahi St.Karimkhan Zand St. Tehran.Iran

City

Tehran

Province

Tehran

Postal code

1598718311

Phone

+98 21 4216 0405

Fax

+98 21 8894 8217

Email

yashospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehdi Rajabnia-Deputy Head of Finance

Department of the Faculty of Medicine

Street address

Finance Department of the Faculty of Medicine Babol University of Medical Sciences, Gangafrroz Ave., Babol, Mazandaran.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 9592

Fax

+98 11 3219 0181

Email

info@mubabol.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Samane Sefatbagha

Position

Student of Master of Neonatal Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Babol University of Medical Sciences, Gangafrroz Ave., Babol, Mazandaran.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 9592

Fax

+98 11 3219 9936

Email

info@mubabol.ac.ir

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

Babol University of Medical Sciences

Full name of responsible person

Dr. Yadollah Zahedpasha

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Babol University of Medical Sciences, Gangafrouz Ave., Babol, Mazandaran.Iran

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 2033

Fax

+98 11 3219 9936

Email

Yzahedpasha@yahoo.com

Web page address**Latest degree**

Bachelor

Other areas of specialty/work

Nursery

Street address

Babol University of Medical Sciences, Gangafrouz Ave., Babol, Mazandaran.Iran.

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3219 9592

Fax**Email**

sefatbagha@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information.

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

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

Babol University of Medical Sciences

Full name of responsible person

Samane Sefatbaqa

Position

Student Master of Neonatal Nursing