

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluating of Two Nutrition Methods Cup Feeding and Finger feeding on Weight Gain and Nutrition Tolerance in Preterm Infants hospitalized in neonatal intensive care unit

Protocol summary

Study aim

Determining and comparing the effect of two feeding methods with cup and finger on weight gain and feeding tolerance of premature infants

Design

this randomized clinical trial study was done on 90 eligible preterm infants in two experimental groups and control group .Lottery method was used for randomization

Settings and conduct

after obtaining permission from the university ethics committee, the samples selected according to the inclusion and exclusion criteria from NICU. After obtaining informed and written consent from the parents to participate in the study, the samples were randomly divided into three groups including a control group and two experimental groups 1 and 2. In the experimental group No. 1, the infants were fed with a cup, in the experimental group No. 2, the infants were fed with a finger, and in the control group, the infants were fed by routine ward method. In this study, the nurse in charge of data recording and data analysis specialist was unaware of the groups.

Participants/Inclusion and exclusion criteria

inclusion criteria including Infants with a gestational age of 32 to 36 weeks, inability to breastfeed exclusion criteria :Term and post-term infants, feeding in other ways before the study, infants with anomalies such as neural and heart and respiratory, congenital diseases of the head and neck, necrotizing enterocolitis, genetic syndromes, infants in need of resuscitation and mechanical ventilation, Apgar score less than 5 in the fifth minute , grade 3 and 4 intracranial hemorrhage, sepsis, respiratory disorders

Intervention groups

Three groups were : including one control group and two experimental groups .group No. 1 were fed with cups, in

the experimental group No. 2 neonates were fed with finger and in the control group (3) the infants were fed by routine method.

Main outcome variables

Weight, feeding tolerance of premature infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100411003679N2**

Registration date: **2021-01-30, 1399/11/11**

Registration timing: **retrospective**

Last update: **2021-01-30, 1399/11/11**

Update count: **0**

Registration date

2021-01-30, 1399/11/11

Registrant information

Name

Khadijeh Dehghani

Name of organization / entity

Shahid Sadoughi University Of Medical Sciences,
Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1751

Email address

dehghanish@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-04, 1399/03/15

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

2020-06-04, 1399/03/15

Actual recruitment end date

2020-10-21, 1399/07/30

Trial completion date

2020-10-21, 1399/07/30

Scientific title

Evaluating of Two Nutrition Methods Cup Feeding and Finger feeding on Weight Gain and Nutrition Tolerance in Preterm Infants hospitalized in neonatal intensive care unit

Public title

Evaluating of Two Nutrition Methods Cup Feeding and Finger feeding on Weight Gain and Nutrition Tolerance in Preterm Infants

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

gestational age 32-36 weeks inability to breast feeding

Exclusion criteria:

term and post term infants feeding in other ways before the study neonates with neural and cardiac and respiratory abnormalities, congenital diseases of the head and neck, necrotizing enterocolitis, genetic syndromes infants in need of resuscitation, Apgar score less than 5 in the 5 minute, infants in need of mechanical ventilation Grade 3 and 4 intracranial hemorrhage, sepsis, respiratory disorders

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **87**Actual sample size reached: **83****Randomization (investigator's opinion)**

Randomized

Randomization description

For random allocation of samples, the lottery method was used. Three identical envelopes were prepared and a number was placed in each envelope, with number 1 representing infants with cups, experimental group 2 representing infants with a finger, and in control group 3 infants fed by routine method. Then one of the nurses who was not aware of the contents of the envelope was asked to choose one of the envelopes and the group of infants is determined according to the number in the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

The research assistant nurse was not aware of the group research to record information about nutrition and weight tolerance. Also, the data analysis expert was unaware of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics.research.ac.ir

Street address

Bahonar Square, the central building of Yazd University of Medical Sciences

City

yazd

Province

Yazd

Postal code

8916978477

Approval date

2020-02-05, 1398/11/16

Ethics committee reference number

IR.SSU.REC.1398.211

Health conditions studied**1****Description of health condition studied**

weighning and feeding tolerance

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Average weight of premature infants

Timepoint

The mean weight of premature infants in three groups was measured before the intervention and then daily at the beginning of the morning shift before feeding and after the intervention.

Method of measurement

The weight of uncoated infants was measured by a special weight scale for infants with zyklus med model and an accuracy factor of 5 grams by the researcher from trained personnel working in the department and recorded in a special form.

2

Description

Percentage of feeding tolerance of premature infants

Timepoint

Before the start of each feeding

Method of measurement

To evaluate the feeding tolerance of infants, before the start of each feeding, the remaining amount of milk was measured using a syringe attached to the gastric catheter by gastric lavage. If this rate was more than 30% of breastfed or any of the clinical symptoms such as distension, vomiting, blood in the stool and fecal remnants, the cause of intolerance to nutrition was considered and recorded in the registration form.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Infants was fed by cup 4 times a day for 7 days, each time for 15-20 minutes. In this group, the infants were kept securely in a blanket in a sitting or semi-sitting position, and the infant's body was placed level. The milk from the mother or from the human milk bank was placed in a small cup, usually 30 to 50 cc in size, with the edge of the cup tangential to the baby's lower lip. With the movements of the tongue, the baby began to suckle. Feeding was completed when the predetermined volume of milk was consumed. The rate of rejection of milk or wasted milk by weighing the gas placed under the chin by a digital scale with a sensitivity of one tenth of a gram, which differed from the weight of infants Weighed.

Category

N/A

2

Description

Intervention group: The finger feeding technique was performed in a manner similar to that described by Fuji Naga et al., 2016. First, the tip of the feeding tube was cut and fixed with adhesive tape into the little finger of the glove. The finger pad was then inserted upwards into the baby's mouth and in front of the roof of his mouth. As the baby began to suck his finger, he gently pressed the plunger onto the syringe and the milk was drawn into the baby's mouth. So, the baby was eager to suck and swallow milk.

Category

N/A

3

Description

Control group: In the control group, feeding was performed routinely. In the routine method, infants were

fed by droppers. In the drip feeding, the baby's head and torso were placed at an angle of 35 to 45 degrees and the prescribed amount of milk was reduced from the volume of the gavage and given with the drip.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd, Neonatal Intensive Care Unit

Full name of responsible person

khadijeh deghani

Street address

Ibn Sina St., Shahid Sadoughi Hospital, Yazd

City

Yazd

Province

Yazd

Postal code

8916886938

Phone

+98 35 3822 4000

Email

medschool@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr masoud mirzaei

Street address

Bahonar Boulevard, the central building of Shahid Sadoughi University of Medical Sciences, Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3724 0171

Email

yazd.ircme@ssu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Province
Yazd
Postal code
8916978477
Phone
+98 35 3824 1751
Email
dehghanish@ssu.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
khadijeh dehghani
Position
nursing instructor, faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Bouali St., Shahid Sadoughi School of Nursing and
Midwifery, Yazd
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3824 1751
Email
info@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
khadijeh dehghani
Position
academic member, nursing instructor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Safaieh, Bouali St., Shahid Sadoughi School of Nursing
and Midwifery, Yazd
City
yazd

Person responsible for updating data

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
khadijeh dehghani
Position
nursing instructor , faculty member
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Bouali St., Shahid Sadoughi School of Nursing and
Midwifery, Yazd
City
yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3824 1751
Email
dehghanish@ssu.ac.ir

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

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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