

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

The investigation effectiveness of cue-based feeding in Comparison with the traditional approach in preterm infant in neonatal intensive care unit

Protocol summary

Study aim

The investigation effectiveness of cue-based feeding in Comparison with the traditional approach in preterm infant in neonatal intensive care unit

Design

Preterm infants will be entered into the study group by blocked random sampling. The block sampling method is to first create 4 blocks in each block of each group in equal numbers and then will be select a block from the blocks.

Settings and conduct

Participants will be recruited from the population of preterm infants in the neonatal intensive care unit at Dr Shariati hospital in Tehran born 34 week and less than 34 weeks' gestational age.

Participants/Inclusion and exclusion criteria

Preterm infants 34 week and less than 34 weeks' gestational age at birth, Infant don't able to oral feeding, Infants that don't have neurological disorders, gastrointestinal disorders, or major congenital anomalies and Apgar score 3 or more in first one minutes and 5 or more in the five minutes will be

Intervention groups

cue-based feeding when they show cue be feeding

Main outcome variables

infant's specifications such as gestational age, sex, Weight gain (grams per day, or grams per kilogram per day), duration of hospital admission: Postmenstrual age (days from birth) to discharge to home from hospital. Age (postmenstrual age and days from birth) at establishment of full oral feeding (independent of intragastric tube feeding), age of oral feeding start and duration of full oral feeding will be recorded in a demographic questionnaire at the baseline assessment. All outcome measures will be measured by the researcher at baseline, start of oral feeding, full oral feeding and the final treatment session (discharge), and at a follow-up measurement after 2 weeks Readiness assessment Scale(POFRSS):

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20180611040062N1**

Registration date: **2018-10-17, 1397/07/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-17, 1397/07/25**

Update count: **0**

Registration date

2018-10-17, 1397/07/25

Registrant information

Name

Farideh Kamran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-21, 1397/03/31

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2018-09-22, 1397/06/31

Actual recruitment end date

2019-05-22, 1398/03/01

Trial completion date

2019-06-23, 1398/04/02

Scientific title

The investigation effectiveness of cue-based feeding in Comparison with the traditional approach in preterm infant in neonatal intensive care unit

Public title

The investigation effectiveness of cue-based feeding in Comparison with the traditional approach in preterm infant in neonatal intensive care unit

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Preterm infants 34 week and less than 34 weeks' gestational age at birth and Apgar score 3 or more in first one minutes and 5 or more in the five minutes
Infants that don't have neurological disorders, gastrointestinal disorders, or major congenital anomalies
respiratory, cardio conditions be stable Infant don't able to oral feeding

Exclusion criteria:

Family' loss of interest to continue in the study
Unstable condition of the infant
Remove the infant from the study in case of weight loss and increase the severity of the infant's problem

Age

From **182 days** old to **238 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

infant is participant who dont have aware

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Tehran university of medical

science

Street address

enqelab Ave,shemron, school of rehabilitation

City

Tehran

Province

Tehran

Postal code

1563663313

Approval date

2018-06-21, 1397/03/31

Ethics committee reference number

IR.TUMS.FNM.REC.1397.010

Health conditions studied

1

Description of health condition studied

preterm infant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

age of oral feeding start

Timepoint

during intervention

Method of measurement

number of day

2

Description

duration of full oral feeding

Timepoint

after intervention (discharge)

Method of measurement

number of day

Secondary outcomes

1

Description

Weight

Timepoint

before intervention

Method of measurement

balance

2

Description

The assessment of the infant's oral feeding readiness

Timepoint

before intervention/start oral feeding day/ full oral feeding day/ discharge day

Method of measurement

3**Description**

Early feeding skills

Timepoint

start oral feeding day/ full oral feeding day/ discharge day

Method of measurement

Early feeding skill scale

4**Description**

duration of hospital admission

Timepoint

after intervention(discharge day)

Method of measurement

day

Intervention groups**1****Description**

Intervention group: Initially, infants will be evaluated 15 minutes before feeding by the oral feeding readiness assessment scale. If infant receive a score of more than 30, they will be prepared for oral feeding and, also will be begin oral feeding by a neonatal specialist diagnosis, and will use a Early feeding skill scale to get a profile of the infant's early feeding skills. When neonates reached 32 PMA no longer received mechanical ventilation, and tolerated full enteral feedings, physicians ordered assessment of the infants' readiness for oral feedings during each scheduled care time, typically every 3 hours. At morning to afternoon, speech-language pathology reviewed infants' scores on the Oral Feeding Readiness Scale. When infants achieved scores of 4 or 5 at 50% or more of their feeding times, health care providers ordered to begin cue-based oral feedings. Infants were offered oral feedings each time their readiness scores were 4 or 5. Speech-language pathology continuously evaluated the quality of oral feedings for preterm infants on the Oral Feeding Quality Scale. An oral feeding was discontinued if the infant demonstrated two disengagement or distress cues (e.g., behaviors scored as 0 or 1 on the scale, such as falls asleep, nasal flaring, arching, or an uncoordinated suck-swallow-breathe pattern that resulted in bradycardia or oxygen desaturation). Each oral feeding could last up to 30 minutes, at which time the remaining milk was gavage fed. Infants continued on the cue-based feeding protocol until they were able to take their prescribed volume orally at each feeding. However, if the infant receives less than 30 scores in the assessment of oral feeding readiness, it is not ready for oral feeding. According to oral infant's skills, interventions such as oral non-nutritional sucking, skin to skin contact will be do before feeding with the tube at the time when the infant reaches to oral feeding.

Category

Rehabilitation

2**Description**

Control group: Initially, infants will be evaluated 15 minutes before feeding by the oral feeding readiness assessment scale. If infant receive a score of more than 30, they will be prepared for oral feeding and, also will be begin oral feeding by a neonatal specialist diagnosis, and will use a Early feeding skill scale to get a profile of the infant's early feeding skills. Feedings are begun on a timed or scheduled basis without regard to infant status. Infants are awakened from sleep to feed. Successful feeding is measured by volume intake, regardless of infant behaviors

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

shariati hospital

Full name of responsible person

farideh kamran

Street address

north kargar Ave, shariat hospital

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

dr shadmehr

Street address

دانشکده توانبخشی، پیچ شمرون، خیابان انقلاب

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

farideh kamran

Position

master

Latest degree

Master

Other areas of specialty/work

Speech therapy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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