

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of Cue-Based Feeding in attainment of full oral feeding in premature infants

Protocol summary

Study aim

determination of effect of Cue-Based Feeding in attainment of full oral feeding in premature infants

Design

Cue-Based Feeding

Settings and conduct

This study is a non-randomized clinical trial. premature neonates 26-32 weeks of embryonic admission in the neonatal intensive care unit at Mashhad Hospital in om al-Binin (Mashhad, Iran).

Participants/Inclusion and exclusion criteria

Criteria for entering the study: Preterm infants are 26-32 PMA Total intestinal feeding volume and completion of intravenous feeding period Infants Needing for gavage feeding Exit criteria: Premature infants requiring respiratory protection by invasive or non-invasive mechanical ventilation Infants with IVH Grade 3 and 4 • Infants with abnormalities require surgery • Babies who are discharged before they have full oral nutrition or are transferred to another hospital • Infants with sepsis • Newborns of alcoholic and addicted mothers • Infants who are taking sleepy or sedative medications such as phenobarbital, midazolam, fentanyl or morphine. • Infants who lose weight or lose weight after the start of the study for 3 consecutive days

Intervention groups

Cue-Based Feeding

Main outcome variables

time of full oral feeding in premature infants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161101030633N3**

Registration date: **2018-01-27, 1396/11/07**

Registration timing: **retrospective**

Last update: **2018-01-27, 1396/11/07**

Update count: **0**

Registration date

2018-01-27, 1396/11/07

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3825 8185

Email address

tataris1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Cue-Based Feeding in attainment of full oral feeding in premature infants

Public title

The effect of Cue-Based Feeding in attainment of full oral feeding in premature infants

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

PRETERM INFANT 26-32w Total intestinal feeding volume

and completion of intravenous feeding period Need feeding by gavage method

Exclusion criteria:
intubation or ncpap IVH 3-4 Need surgery sepsis opiom Taking hypnotic or sedative medications Weight loss or weight loss for 3 days Discharge or transfer to another hospital Neonatal abnormalities require surgery

Age
From **6 months** old to **8 months** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **30**
control group=30 Intervention group=30

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
... .

Placebo
Not used

Assignment
Other

Other design features
This study is the only study that has been conducted in Iran regarding cue based feeding on neonates' and specially performed in immature newborns of 26-32 week, similar studies performed abroad were premature infants 26-36 week has been reviewed. Since nutritional behavior and development in newborns are completely different before and after 32 weeks, our study has considered this difference and immature newborns have been considered for behavioral and nutritional evolution.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی یزد

Street address

ba honar

City

yazd

Province

Razavi Khorasan

Postal code

0000000000

Approval date

2016-11-08, 1395/08/18

Ethics committee reference number

185127/1/17/پ

Health conditions studied

1

Description of health condition studied

preterm

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Achieving full oral nutrition

Timepoint

Time to stop iv- therapy until Exit time of the catheter

Method of measurement

Weighing and Achieving Evolutionary Skills and Discharge

Secondary outcomes

1

Description

Weighin

Timepoint

daily

Method of measurement

Basque Scale (seca)

Intervention groups

1

Description

Intervention group:

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

om-al-banin Hospital in Mashhad-NICU

Full name of responsible person

HEIDARZADE MOHAMMAD

Street address

ayatollah bahjat st

City

MASHAD

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Razavi Khorasan

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9144734756

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Email

tataris1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr mohammad por

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Email

salimi@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

90

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

Yazd University of Medical Sciences

Full name of responsible person

tahere salimi

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

mohammad heidarzade

Position

Associate professor-Consultant

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

samane tatari

Position

nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

bahjat ts

City

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Razavi Khorasan

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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