

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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

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ayatollah bahjat st

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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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safaie st

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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**

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

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bahjat ts

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**Postal code**

9144734756

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**Email**

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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