

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Assessment of the effect of a nutritional readiness care plan on the length of time from non-oral to full-oral nutrition in the hospitalized premature infants in neonatal intensive care unit of Isfahan University of medical Sciences 2011

#### Protocol summary

##### Summary

The present study investigated the effects of nutritional feeding readiness care plan on the length of time from non-oral to full-oral nutrition. The entry criteria included no medical complication such as head and face malformations and intraventricular hemorrhage and excluded criteria included to be NPO or intubation. The 50 preterm infants were recruited from two hospitals of Isfahan( Beheshti and Alzahra) and after parental consent was obtained, were randomized in to experimental and control group (25 males, 25 females) participated in the study that included hospitalized in neonatal intensive care unit. The babies had feeding readiness program for 7 sequential days (twice a day at 4 evening and 9 at night) that started from the first non-oral feeding (gavage) day .Then the length of time from non-oral to full-oral nutrition was measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012071110249N1**

Registration date: **2012-08-30, 1391/06/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-08-30, 1391/06/09

##### Registrant information

###### Name

Somayeh Rostamli

**Name of organization / entity**

Isfahan University

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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###### Recruitment status

**Recruitment complete**

###### Funding source

Nursing and Midwifery Faculty of Isfahan University of Medical Sciences.

###### Expected recruitment start date

2012-02-29, 1390/12/10

###### Expected recruitment end date

2012-08-10, 1391/05/20

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Assessment of the effect of a nutritional readiness care plan on the length of time from non-oral to full-oral nutrition in the hospitalized premature infants in neonatal intensive care unit of Isfahan University of medical Sciences 2011

###### Public title

Assessment of the effect of a nutritional readiness care plan on the length of time from non-oral to full-oral nutrition

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion criteria: premature infants with gestational ages between 28-34 weeks ; after at least 48 hours of oxygen therapy with CPAP High flow ; intubation or oxygen flow in incubator ; the first day of non-oral feeding ; they will stay until the end of study. Exclusion criteria: neonates with head-facial malformation ; cardiopulmonary diseases with respiratory distress and limb cyanosis ; neurovascular malformations ; hydrocephaly ; microcephaly ; Enterocolitis necroticans ; chronic lung diseases ; Intraventricular hemorrhage (more than grade II) ; Periventricular leukomalacia ; 18 or 21 trisomy ; The proven metabolic diseases ; anticonvulsant drug use ; phototherapy ; sudden change position in neonates with Intraventricular hemorrhage or hypoxia or gastrointestinal diseases such as Enterocolitis necroticans or to be NPO ; or Intubation ; surgical procedures ; avoiding with doctor's orders ; sudden death.

#### Age

To 1 year old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 50

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary IDs

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Nursing and Midwifery Faculty, Isfahan Medical University Sciences

##### Street address

Hezar Jarib Steert, Isfahan Medical University Sciences

##### City

Isfahan

##### Postal code

81746-73461

#### Approval date

2012-01-17, 1390/10/27

#### Ethics committee reference number

390433

## Health conditions studied

### 1

#### Description of health condition studied

premature feeding

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

length of time from non-oral to full-oral nutrition

#### Timepoint

after 7 days

#### Method of measurement

checklist

## Secondary outcomes

### 1

#### Description

jaw and tongue position

#### Timepoint

full feeding time

#### Method of measurement

NOMAS

## Intervention groups

### 1

#### Description

At first some stimulation (through 3 minutes) for increasing the neonate's alertness such as audible, tactile, visible and vestibular were done in incubator then infants' level of alertness was coded from observations based on a modification of the neonatal behavioral assessment scale' state definitions. Then the baby had weighted on a calibrated neonatal scale. Pre-oral phase included stimulation of cheek and lips (with right hand in all participants) through 7 and intra-oral stimulation included of gums, upper palate, inner cheeks, middle blade of tongue, and non-nutritive sucking for 7 minutes such as table 1 and after 1 minute resting allowed the infant to suck on finger for 2 minutes. After feeding the baby put in prone position and her/his hands put near the mouth.

#### Category

Treatment - Other

### 2

#### Description

The control group put on the cardio-pulmonary monitoring and the researcher only placed her hands from the valves of incubator for 16 minutes infant twice a day but did not touch them.

**Category**

Treatment - Drugs

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

Alzahra/ Beheshti hospital

**Full name of responsible person**

Dr Zohreh Badiie

**Street address**

Alzahra hospital, Hezar jarib street, Isfahan

**City**

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

Isfahan Medical University Science

**Full name of responsible person**

Zargham Broujeni Ali

**Street address**Hezar jarib street , Nursing and Midwifery Faculty,  
Isfahan Medical University Science**City**

Isfahan

**Grant name****Grant code / Reference number**

390433

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

Yes

**Title of funding source**

Isfahan Medical University Science

**Proportion provided by this source**

100

**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Isfahan Medical University Science

**Full name of responsible person**

Somayeh Rostamli

**Position**

MS student

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**Nursing and midwifery faculty , Isfahan Medical  
University Sciences**Full name of responsible person**

Zargham Broujeni Ali

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Phd

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Nursing and Midwifery Faculty

**Full name of responsible person**

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*