Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity

Isfahan University

Country

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Recruitment status

Recruitment complete

Funding source

Nursing and Midwifary 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

Inclution critria: prematures infants with gestational ages between 28-34 weeks ; after at least 48 hour of oxytion therapy with CPCP High flow ; intubation or o2 flow in incubator ; the first day of non-oral feeding ; they will stay until the end of study. Exclusive criteria: neonates with head-fatial malformation ; cardiological diseasese with respiratory distress and limbs syanosis ; noromascular malformations ; hydro cephaly ; micro cephaly ; Enteroclysis necrosan ; choronic lung diseases ; Intraventricular hemorrhage(more than grade II) ; Periventricular leukomalacia ; 18 or 21 trisomia ; The proven metabolic diseases ; anticonvalsant drug use ; phototerapy ; sudden change position in neonates with Intraventricular hemorrhage or hypoxia or gastrointestinal diseases such as Enteroclysis necrosan or to be NPO ; or Intubation ; surgical prosidures ; avoiding with doctors 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

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Isfahan

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81746-73461

Approval date
2012-01-17, 1390/10/27

Ethics committee reference number
390433

Health conditions studied

1

Description of health condition studied
prematures 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
cheklist

Secondary outcomes

1

Description
jaw and toungh tongue position

Timepoint
full feeding thme

Method of measurement
NOMAS

Intervention groups

1

Description
At first some stimulation (through 3 minutes) for increasing the neonate’s alertness such as audible, tactical, 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 participant) through 7 and intra-oral stimulation included of gums, upper palate, into cheeks, middle blade of tonue, and non-nutritive sucking for 7 minutes such table1 and after 1 minutes 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 Badiee
Street address
Alzahra hosptal,Hezar jarib street,Isfahan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan Medical University Science
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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

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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