

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical Trial of Effect of Pacifier on physiologic criteria and feeding tolerance in preterm infant According to the NHS(national health system) Guideline of NNS.

Protocol summary

Summary

Aim: Effect of pacifier on physiologic criteria and feeding tolerance in preterm infants. In this Clinical trial, 76 preterm infants Weighing 1500 gr or less and gestational age was 32 weeks and less, selected (if they have including criteria) and divided into two groups of 38 intervention and control groups. Infants in the control group received routine care but the infants in the intervention group received pacifier 10 minutes before feeding, during and after feeding as long as the infant is not willing to suck a pacifier. According to the National Health Service guideline of nonnutritive sucking, it repeated in every feeding time. Pacifier didn't push into the infant's mouth by force, but first gently touch the lips and around the infant's mouth. If opened his mouth put a pacifier into the mouth and on the tongue. To keep the pacifier brought the infant to his mouth to hold a pacifier or the researcher was kept quiet. For both groups list of feeding tolerance including residue, distension, vomiting and defecation were completed 4 times in 24 hours. The intervention lasted for 20 days and the two groups were compared using statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060628295N1**
Registration date: **2017-01-28, 1395/11/09**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-28, 1395/11/09

Registrant information

Name

Parisa Rahnama

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Science

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of Effect of Pacifier on physiologic criteria and feeding tolerance in preterm infant According to the NHS(national health system) Guideline of NNS.

Public title

Effect of pacifier in preterm infant

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age between 26 to 32 weeks according to the Ballard scale; Age of birth up to

48 hours; birth weight less than 1500 g; no previous feeding (Along with the study, tube feeding for the infant begins); Lack of respiratory distress requiring intubation and ventilator; Lack of asphyxia; Lack of mother addiction; Having first and the fifth minute Apgar score above 7; No anomaly of the jaw, mouth and gastrointestinal tract like cleft lip, cleft palate and Esophageal atresia. Exclusion criteria: Feeding intolerance and NPO during the study; The need for intubation during study; The incidence of NEC during the study; Intraventricular hemorrhage (grade 3 and 4); Hospital Stay less than 7 days; Sepsis during the study; The reluctance of parents to continue to participate in the study.

Age

To **31 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

With sortition between two groups, first group was determined. Sampling was started at control group and when it was finished, the intervention group was sampled. Oral feeding disruption, sepsis and intracranial haemorrhage caused the infant out of study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Mashhad University Of Medical Science

Street address

Daneshgah Street

City

Mashhad

Postal code

Approval date

2016-01-16, 1394/10/26

Ethics committee reference number

research/940959/1/920

Health conditions studied

1

Description of health condition studied

Feeding tolerance and physiologic criteria in preterm infants

ICD-10 code

P07

ICD-10 code description

Disorders related to short gestation and low birth weight, not elsewhere classified

Primary outcomes

1

Description

Physiologic criteria including Heart rate, respiratory rate and o2 saturation

Timepoint

every 6 Hour

Method of measurement

with pulse oxymetry and counting respiratory rate

2

Description

feeding tolerance including vomiting, residue, abdominal distension and defecation

Timepoint

every 6 Hour(6,12,18,24)

Method of measurement

Observation and complete the checklist

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

infants in intervention group recieved pacifier according to the NNS guideline 10 minute before feeding, during and after feeding until the infant wants to suck the pacifier. The pacifier was used in this trial, was spesify for premature infants and manufactured by Philips company in Germany and it is only for hospital use.

Category

N/A

2

Description

Control group:infants in control group just take routine care and didn't received pacifier.every 6 hour,we filled the checklist for them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Omolbanin Hospital

Full name of responsible person

Parisa Rahnama

Street address

Ayatollah Behjat 16, Ayatollah Behjat Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research, Mashhad University Of Medical Sciences

Full name of responsible person

Tayebeh Reyhani

Street address

Daneshgah street

City

Mashhad

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor For Research, Mashhad University Of Medical Sciences

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

Mashhad university of medical science

Full name of responsible person

Parisa Rahnama

Position

Master student of Neonatal Intensive Care nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Neonata IHealth Office

Full name of responsible person

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Position

Assistant Professor

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

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Position

Master student of Neonatal Intensive Care nursing

Other areas of specialty/work

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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