Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Determine the effect of abdominal palpation on the prevention of feeding intolerance in the right lateral position and heads-up in premature infants.

Protocol summary

Summary

The aim of this study is to determine the abdominal palpation on the prevention of feeding intolerance in preterm infants. The study population includes 54 premature infants that hospitalizes in neonatal intensive care units and nurseries. They will be selected based on inclusion and exclusion criteria (such as 28 to 32 weeks of gestational age ; 1800-1000Grm weight and no abnormal naso pharyngeal area) placed nonrandomly in two groups, by using the cart.The first baby that be entered to NICU, assigned to the intervention or control group randomly and then, newborns are placed next to intervention and control groups, respectively. The research intervention is a kind of palpation that performs on the abdomen for 15 minutes. Palpation technique will be done by the researcher for 4 days and 2 times a day (once in the morning, once at night) in the intervention group. During this period, vomiting and stool also will be recorded. On the fifth day, the result will be compared with control group.The main outcome of this study is feeding tolerance. Feeding tolerance promotes preterm infants. In this intervention, Olive oil is used for every touch section. Olive oil creates less sensitivity in newborns.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102430474N1**
Registration date: **2017-02-24, 1395/12/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-24, 1395/12/06

Registrant information

Name
Azam Shirinabadi Farahani
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Recruitment status

Recruitment complete

Funding source

by my own

Expected recruitment start date

2016-11-20, 1395/08/30

Expected recruitment end date

2017-04-19, 1396/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determine the effect of abdominal palpation on the prevention of feeding intolerance in the right lateral position and heads-up in premature infants.

Public title

Determine the effect of abdominal palpation on feeding tolerance in preterm infants.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: preterm infants with 28-32 weeks age; 1800-1000Grm weight; no swallowing reflex; getting enough through the mouth; present of effective swallowing exclusion criteria: abnormal nasopharyngeal area; sepsis; Necrotizing Enterocolitis; obstruction and bowel surgery; cleft lip and cleft palate; intraventricular hemorrhage; the recent restoration of the esophagus; heart disease; respiratory support needs; physiological instability; Changes in baby conditions that cause fasting or require to mechanical ventilation through continuous positive airway pressure.

Age

From **28 days** old to **31 days** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Newborns, based on the date of entry into the neonatal intensive care unit and based on inclusion criteria, will be placed in intervention and control groups respectively. The first newborn entered in the neonatal intensive care unit, was located in the intervention group and next newborn was placed in control group. This process continues until sampling was done.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of International Branch of Shahid Beheshti University of Medical Science

Street address

Number 19, Shahid Abbasspour St., vali-asr Ave.,

City

Tehran

Postal code

141553693

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.221

Health conditions studied

1

Description of health condition studied

Preterm Infants

ICD-10 code

P92.9

ICD-10 code description

Feeding problem of newborn, unspecified

Primary outcomes

1

Description

prevention of feeding intolerance

Timepoint

5 dayes

Method of measurement

Using charts available in the Neonata lIntensive Care Unit

Secondary outcomes

empty

Intervention groups

1

Description

Abdominal palpation in the intervention group.

Category

Prevention

2

Description

No palpation of the abdomen in the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari hospital affiliated with the Urmia University of Medical Sciences

Full name of responsible person

Soheila Badini Pourazar

Street address

Shahid Motahari hospita,Ayatollah Kashani St.,Urmia

City

Urmia

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Behesti University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Shahid Behesti University of Medical Sciences

Street address

Vice chancellor for research, Shahid Behesti University of Medical Sciences, next to Taleghani hospital, Yaman Street, Shahid Chamran highway.

City

Tehran

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, Shahid Behesti 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

School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

PhD in Nursing/Instructor

Other areas of specialty/work

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Web page address

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