

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

To investigate the effect of using pacifier and mother's finger, two ways of non-nutritive sucking, during gavage on physiological parameters in preterm neonates.

Protocol summary

Summary

It was a quasi-experimental study which were done in university hospitals having NICU i Tehran, Iran. Sampling method was continuous. Informed consent was obtained from parents after the nature of study was explained. Due to the number of samples required, infants were enrolled. Once the infant was getting out of NPO, gavage started with breast milk. All infants were in stable and awake state. NNS with mother's finger (already receiving instructions about hand-wash) putting on hypoallergenic disposable gloves started; before, during and after feeding with NGT, on a certain time. Then pulse rate and o2 saturation were recorded of monitor connected to infant. For next time feeding infant received NNS with pacifier and the other feeding gavage were done without any interventions. This recording continued for 4 days. NNS started 5 min before feeding until 5 min after feeding. For all samples breast-milk was used for feeding.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052234086N1**

Registration date: **2017-06-07, 1396/03/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-07, 1396/03/17

Registrant information

Name

Teni Javadian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To investigate the effect of using pacifier and mother's finger, two ways of non-nutritive sucking, during gavage on physiological parameters in preterm neonates.

Public title

To investigate the effect of using pacifier and mother's finger on physiological parameters in preterms.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age of birth 34 to 37 weeks; stable hemodynamic state; breastfeeding; no need to respiratory support; not having apnea events; not receiving analgesic drugs. Exclusion criteria: having metabolic disorders; genetic syndromes; abnormalities in

mouth movements; cognitive disorders; neurological disorders; oral and palatal disorders; sudden changes in physiological parameters; change of milk type.

Age

From **1 day** old to **1 month** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Postal code

Approval date

2016-08-08, 1395/05/18

Ethics committee reference number

IR.IUMS.REC 1395.9311451003

Health conditions studied

1

Description of health condition studied

Effect of non nutritive sucking on physiological parameters

ICD-10 code

P05-P08

ICD-10 code description

Disorders of newborn related to length of gestation and fetal growth

Primary outcomes

1

Description

Heart rate

Timepoint

5 min before gavage, during gavage, 5 min after gavage

Method of measurement

Monitoring

2

Description

Oxygen saturation

Timepoint

5 min before gavage, during gavage, 5 min after gavage

Method of measurement

Monitoring

Secondary outcomes

1

Description

Tachycardia

Timepoint

During intervention

Method of measurement

Monitoring

2

Description

Reduction in oxygen saturation

Timepoint

During intervention

Method of measurement

Monitoring

Intervention groups

1

Description

This intervention is on preterm infants; sing mother's finger and pacifier during feeding with NGTube and during third feeding no intervention is used for infant.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar hospital affiliated to Iran University of Medical Sciences

Full name of responsible person

Dr. Sorour Parvizy

Street address

Ali Asghar hospital, Dastgerdi st.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Ms. Sorour Parvizy

Street address

Nursing Faculty, Yasemi St., Vali e Asr 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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Sorour Parvizy

Position

PhD / nursing education

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