

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The Effect of Non-Nutritive Sucking on the Weight Gaining and the Length of Stay of Premature Neonates Under The Gavage in Neonatal Intensive Care Units of Selected Hospitals Affiliated to Shahid Beheshti University of Tehran

Protocol summary

Study aim

The Effect of Non-Nutritive Sucking on the Weight Gaining and the Length of Stay of Premature Neonates Under The Gavage in Neonatal Intensive Care Units of Selected Hospitals Affiliated to Shahid Beheshti University of Tehran

Design

The clinical trial will have intervention and control groups (with 40 random samples in each group). Mahdiah and Mofid hospitals will be randomly selected as the intervention and control group's hospitals. Then premature infants in the NICU ward of each hospital, who have inclusion criteria, will enter relevant groups.

Settings and conduct

After obtaining the ethics code, the research environment will be randomly selected as a control or intervention group hospital by one of the nurses. After obtaining parental consent, the admitted infants in both intervention or control hospitals, who have inclusion criteria, will enter the relevant group. The infants of both groups will be hugged by the mothers, in order to be certain the infant is awake and the researcher will perform the gavage. In the intervention group, at the same time as the gavage, the non-nutritive sucking intervention will be performed by the mothers.

Participants/Inclusion and exclusion criteria

The neonate has 30 to 37 weeks age. The neonate should be fed for more than 24 hours. Breast milk is only used for feeding. The neonate should have a first minute Apgar score of at least 3 and a fifth-minute Apgar score of at least 5. Infants do not have chronic underlying conditions such as heart problems, respiratory problems, surgery, IVH, and congenital anomalies.

Intervention groups

Intervention group: In this group, non-nutritive sucking will be performed by the mother's little finger at the

same time as the gavage. Control group: Gavage will be performed without the intervention.

Main outcome variables

Weight gaining; Length of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200617047806N1**

Registration date: **2021-01-07, 1399/10/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-07, 1399/10/18**

Update count: **0**

Registration date

2021-01-07, 1399/10/18

Registrant information

Name

Soheila Irani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7773 2567

Email address

sirani.2812@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-21, 1399/07/30

Expected recruitment end date

2021-01-19, 1399/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Non-Nutritive Sucking on the Weight Gaining and the Length of Stay of Premature Neonates Under The Gavage in Neonatal Intensive Care Units of Selected Hospitals Affiliated to Shahid Beheshti University of Tehran

Public title
the effect of non-nutritive sucking on the weight gaining and the Length of Stay of Premature Neonates

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
The neonate gestational age must be between 30-37 weeks. The neonate is not fed more than 24 hours. Breast milk is only used. APGAR score of 3 or more at the first minute, and of 5 or more points at the 5th minute. Neonates must not have chronic diseases like heart diseases, respiratory diseases, surgery, IVH and congenital anomalies
Exclusion criteria:
neonates who have TPN. neonate who can not do non-nutritive sucking for any reason using medicine which affect CNS

Age
From **1 day** old to **2 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
There will be two endorsed cards which are intervention and control hospital. By selecting one of those cards by one of the nurses, the research environment will be divided into an intervention and control group. Therefore, the neonates of the two groups will be selected from the intervention or control hospital.

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

Iran National Committee for Ethics in Biomedical Research

Street address

Valiasr

City

Tehran

Province

Tehran

Postal code

1996835119

Approval date

2020-05-03, 1399/02/14

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.038

Health conditions studied

1

Description of health condition studied

preterm infant

ICD-10 code

P07.3

ICD-10 code description

Preterm [premature] newborn [other]

Primary outcomes

1

Description

weight gaining

Timepoint

To Measure the weight on the first day of entry into the study and then measure it daily until the day which the baby can feed orally

Method of measurement

scales

2

Description

the length of stay

Timepoint

The time difference between the day of hospitalization and the day of discharge

Method of measurement

by using the patients file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first 10 minutes of gavage, the neonates will receive non-nutritive sucking intervention by the mother's little finger. The intervention will be done 3 times in every morning shift during the first 10 minutes of gavage.

Category

Other

2

Description

Control Group: neonates of this group will not receive any intervention during the gavage. in order to delete the mother role as a mediating variable, in both groups mothers will hold their neonates.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiyeh Hospital

Full name of responsible person

NICU Ward

Street address

NO. 7, Garkhaneh Glass Ave., Fadaian-e-Islam Blvd.,
Shoosh Squ

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tehran

Province

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Postal code

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Email

mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin zarghi

Street address

In front of Shahid Rajaei Heart Hospital, Corner of
Niayesh St, Valiasr St.

City

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Province

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1985717443

Phone

+98 21 8877 0065

Email

Sirani.2812@yahoo.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid beheshti university of medical science of Tehran

Proportion provided by this source

1

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soheila Irani

Position

Student of Master of Science

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

School of Nursing and Midwifery, In front of Shahid
Rajaei Heart Hospital, Vali-e-Asr St.

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sirani.2812@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Manighea Nourian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main variables of the study will be published.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Staff and researchers working in universities and health centers

Under which criteria data/document could be used

The data can be published and used only if the identity information of the samples is not identifiable

From where data/document is obtainable

Communicating with researcher: Soheila Irani, sirani2812@yahoo.com

What processes are involved for a request to access data/document

Documentation is possible after the publication of the article via the mentioned e-mail address

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Soheila Irani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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