Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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). Mahdieh 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 to37 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., Fadaiyan-e-Islam Blvd., Shoosh Squ
City
tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 4400 6901
Fax
+98 21 4400 6901
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
Tehran
Province
Tehran
Postal code
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.
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
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
Street address
School of Nursing and Midwifery, Corner of Niayesh st, Valiasr st.
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 8865 5366
Email
manighea@yahoo.com

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
Nursery
Street address
Valiasr
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 7773 2567
Fax
Email
sirani.2812@sbmu.ac.ir

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