Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Non-nutritive sucking with pacifier and finger on weight gaining, initiation of breastfeeding and discharge of preterm newborns, in neonatal intensive care unit, Hazrat Zynab hospital, Shiraz

Protocol summary

Summary

Objectives: Infants born prematurely are vulnerable. Many premature infants because of in coordination between sucking, swallowing and breathing, may need alternative feeding methods, until the development of skills which necessary for oral feeding. Design: 3 groups, single blind randomized control trial. Setting and conduct: Neonatal intensive care unit (NICU) of one university hospital in Shiraz city. Participants: 90 healthy preterm newborns, Fetal age between 30-34 weeks; Birth weight appropriate for gestational age(AGA); Apgar score at 1 and 5 min after birth ≥ 7; Non addicted mothers; No need for phototrapy; No need for complete parental feeding, will randomly assigned to three groups: two experimental groups and control group and will Excluded if Un willingness the parents for complete the study; Need for transfer to other wards or other hospitals; Received drugs that affect central nerves system; Need for surgical and medical interventions during study; Need for photo therapy during study; Received other supportive intervention; Abnormal physiologic response during intervention; Missing of intervention at least twice during study. Intervention: Non-nutritive sucking with finger and pacifier that will be carried out by mothers in 10 first minuets of gavages' feeding, three times a day. Main outcome: Neonate’s weight will be evaluated daily by trained midwife until discharge day, also the initiation of breast feeding and the time of discharge will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106062324N8**
Registration date: **2012-03-17, 1390/12/27**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-03-17, 1390/12/27

Registrant information

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Maryam Keshavarz

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

vice chancellor for research- Tehran University of Medical Sciences

Expected recruitment start date

2011-10-23, 1390/08/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Non-nutritive sucking with pacifier and finger on weight gaining, initiation of breastfeeding and discharge of preterm newborns, in neonatal intensive care unit, Hazrat Zynab hospital, Shiraz

Public title
The impact of non-nutritive sucking with pacifier and finger on weight gaining, initiation of breastfeeding and discharge of preterm newborns.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Fetal age between 30-34 weeks; Birth weight appropriate for gestational age(AGA)); Apgar score at 1 and 5 min after birth, ≤ 7; Normal neonate (no evidence of congenital anomaly such as respiratory and heart problems, seizure, CNS hemorrhage ...); Non addicted mothers; No need for phototherapy; No need for complete parental feeding. Exclusion criteria: Un willingness the parents for complete the study; Need for transfer to other wards or other hospitals; Received drugs that affect central nerves system for example: Phenobarbital and phenytoin; Need for surgical and medical interventions during study; Need for photo therapy during study; Received other supportive intervention such as touch therapy, kangaroo care, music therapy and other intervention during study; Abnormal physiologic response such as heart rate above 200 beat per min or under 100 beat per min, deceleration of oxygen saturation level under 80% during intervention; Missing of intervention at least for two times during study.
Age
To **1 year** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
No
Secondary trial Id
No
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical commitment of Tehran University of Medical Sciences
Street address
Sixth floor ,Central office, Ghods St, Keshavarz Blvd- Tehran, Iran
City
Tehran
Postal code
Approval date
2011-08-11, 1390/05/20
Ethics committee reference number
786

Health conditions studied

1

Description of health condition studied
weight gaining- time of discharge- Initiation of breast feeding
ICD-10 code
P07.3
ICD-10 code description
سن حاملگی کمتر از 28 هفته یا 196 روز کامل

Primary outcomes

1

Description
Weight
Timepoint
Daily
Method of measurement
neonat weight will be taken without cloth on an electronic weighing scale with an accuracy of ± 10 grams.

Secondary outcomes

1

Description
The initiation of breastfeeding
Timepoint
The first time that neonate will be able to sucking and breastfeeding
Method of measurement
Observation and record in checklist

2

Description
The time of discharge
Timepoint

at the time of discharge

Method of measurement

Observation and record in checklist

Intervention groups

1

Description

Non- nutritive sucking with pacifier and finger

Category

Prevention

2

Description

No intervention will be done in control group

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zynab treatment and educational centre

Full name of responsible person

Zahra Rajaee

Street address

Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research- Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotohi

Street address

Sixth floor ,Central office, Ghods St, Keshavarz Blvd- Tehran, Iran

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- Tehran 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 Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Maryam Keshavarz

Position

Assistant Professor in Midwifery Education

Other areas of specialty/work

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Person responsible for updating data

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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