

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 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 phototherapy; 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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Name of organization / entity

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

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Name of organization / entity
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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