Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effectiveness of non-nutritive sucking performed by the mother on the physiological indexes and full oral feeding in premature infants in the neonatal intensive care unit

Protocol summary

Summary
t This research is randomized clinical trial . The research does for 40 neonates in two groups. The goal is the effect of non-nutritive sucking by the mother on the physiological stability and full oral feeding in premature infants. Neonates have 1000-2500 gr weight and 26-34 weeks age of pregnancy. Mothers do intervention with stimulate that neonate suck mother's finger. ،This intervention does 3times in a day(24 hours).physiological sign (breath, heart,O2 Sat)measure in 5 min before, during and 5 min after intervention with pulsoxymetry. In additional amount of milk that be gavage during of intervention had measured. This intervention does until neonate can feed with complete oral feeding.

General information

Acronym
nns
IRCT registration information
IRCT registration number: **IRCT201501205163N2**
Registration date: **2015-06-10, 1394/03/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2015-06-10, 1394/03/20

Registrant information
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Recruitment status
Recruitment complete
Funding source
Tehran University of Medical Sciences

Expected recruitment start date
2015-01-22, 1393/11/02
Expected recruitment end date
2015-08-20, 1394/05/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effectiveness of non-nutritive sucking performed by the mother on the physiological indexes and full oral feeding in premature infants in the neonatal intensive care unit

Public title
Effectiveness of non-nutritive sucking performed by the mother on the physiological indexes and full oral feeding in premature infants in the neonatal intensive care unit
Purpose
Supportive
Inclusion/Exclusion criteria
inclusion criteria: neonate: age of pregnancy 26-34 weeks; weight 1000-2500gr; score of apgar in 1 &5 minuets were above 7; was normal without congenital & respiratory and heart disease; have not respiratory assistant; do no use any drug can effect on respiratory and nervous system; not use other kind of complementary care; have normal physiologic sign mother: do not use drug or alcohol; can do two

intervention a day; has not scare in finger Exclusion criteria: Mother does not want to do intervention; neonate can not tolerate intervention or will change situation

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

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
Tehran University Medical Sciences

Street address
Qudes St - Keshavarz Bol

City
Tehran

Postal code
1473656169

Approval date
2015-01-14, 1393/10/24

Ethics committee reference number
93-04-28-27919

Health conditions studied

1

Description of health condition studied
complete breast feeding

ICD-10 code
P92.8

ICD-10 code description
Other feeding problems of newborn

Primary outcomes

1

Description
Phisiologic signs

Timepoint
Before/during/after intervention

Method of measurement
pulsoximetry

2

Description
vital signe

Timepoint
before/ after and during of trial

Method of measurement
pals oximetry

Secondary outcomes

1

Description
complete feeding through mouth

Timepoint
when order the physition

Method of measurement
with C.C of feeding

2

Description
Oral feeding

Timepoint
ordered by physician

Method of measurement
c.c milk

Intervention groups

1

Description
control: Rotine nursing intervention

Category
Rehabilitation

2

Description
intervention: Non nutrition sucking buy sucking of mother's finger

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran university medical sciences
Full name of responsible person
Akram sadat sadat hoseini
Street address
Tohid squire- faculty of nursing and midwifery
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University Medical Sciences
Full name of responsible person
Mohammad Ali Cheraghi
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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
Tehran University 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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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