

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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

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

Name

Akram sadat Sadat hoseini

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

Phone

+98 21 6653 2998

Email address

ashoseini@tums.ac.ir

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

Physiologic 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

Street address

Faculty of nursing and midwifery- Tohid squire

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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****Contact****Name of organization / entity**

Tehran University Medical Sciences

Full name of responsible person

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Web page address**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