Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Assessment of the effect of integrated mother's milk odor and Nonnutritive Sucking on the time of achievement independent oral feeding in preterm neonates

Protocol summary

Summary

The aim of this study is evaluation of the effect of Integrated Mother's Milk Odor with Nonnutritive Sucking (NNS) on the time of achievement of the independent oral feeding in preterm infants (34 infants; 17 in intervention and 17 in control group). The study will be accomplished in the trail phase two with simple randomization. Blinding will be applied with mothers of the infants (single blind) and they will not be aware of the method. The 28-32 gestational weeks newborns who will hospitalize in Tehran Mahdiye and Shohadaye Tajrish hospital will be recruited in this study. Eligibility criteria consistence of Apgar score more than 6 in fifth minute after birth, minimum weight 1000 gr at birth and the ability of gavage tolerance. Newborns with any kind of congenital abnormalities or disease and sepsis will be excluded. Both groups will receive NNS, intervention group will receive the odor stimulation via cotton soaked in their mother’s milk, at first 5 minute of gavage feeding ,three times daily during 10 continuously days; control group will receive NNS and a piece of dry cotton. Primary outcome will be to decrease the time of achievement of independent oral feeding, and secondary outcomes will be to increase the average of weight gain, to decrease the hospitalization in intervention group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082829574N1**
Registration date: **2017-01-03, 1395/10/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-01-03, 1395/10/14

Registrant information

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Recruitment status

Recruitment complete

Funding source

Myself

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of integrated mother's milk odor and Nonnutritive Sucking on the time of achievement independent oral feeding in preterm neonates

Public title

The effect of mother milk odor and nonnutritive sucking on independent feeding

Purpose

Treatment

Inclusion/Exclusion criteria

Eligibility criteria: The gestational age between 28 and 32 weeks and 6 days at birth; Being Started gavage feeding and tolerated it by the infant; The minimum birth weight 1000 gram; The physiological stability (heart rate, blood pressure, respiratory rate and oxygen saturation according to age) during the 24 hours before intervention; The Apgar score more than 6 at fifth minute after birth; The signed consent form by parents.
Exclusion criteria: Newborn with congenital malformations; chromosomal abnormalities; intraventricular hemorrhage grade 3 and 4; necrotizing enterocolitis; asphyxia and neonatal seizures; neonatal jaundice leading to blood transfusions and positive sepsis work up; transfer to another hospital

Age

From **3 days** old to **12 days** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **34**

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

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Univesity of Social Welfare and Rehabilitation

Street address

Kodakyar Ave., Daneshjo Blvd.,Evin

City

Tehran

Postal code

1985713834

Approval date

2016-10-03, 1395/07/12

Ethics committee reference number

IR.USWR.REC.1395.210

Health conditions studied

1

Description of health condition studied

To achieve independent oral feeding in preterm infants

ICD-10 code

p92.2, p92

ICD-10 code description

Slow feeding of newborn; Neonatal difficulty in feeding at breast; Feeding problem of newborn, unspecified

Primary outcomes

1

Description

Time to achieve 8 time independent oral feeding

Timepoint

During and after intervention until the 8 times independent feeding

Method of measurement

Nursery report of independent feeding via breast milk or bottle feeding

Secondary outcomes

1

Description

echological age discharge time

Timepoint

before the intervention, birthday until discharge time

Method of measurement

The days after birth until discharge time

2

Description

Newborn's age according to last menstrual period (LMP) at discharge

Timepoint

At discharge time

Method of measurement

The days from last menstrual age (LMP) until the discharge day

3

Description

Average weight intake during two weeks after the intervention

Timepoint

Concurrently with intervention, daily during 2 weeks

Method of measurement

Seca baby electrical scale 354 produced by German company

Intervention groups

1

Description
Intervention Group1: In intervention group1 the odor stimulation will be used concurrently with Nonnutritive Sucking (NNS) in first 5 minutes of gavage feeding for 3 times consecutively during 10 days without stop. The odor stimulation include a piece of cotton soaked in daily mother's milk that is in body temperature. This cotton will be put 2-3 cm near the nose of the newborn. The NNS will be performed by using the gloved small finger that stroke the palate to stimulate sucking.

Category
Treatment - Other

2

Description
Group2 (Control): In control group only the NNS in first 5 minutes of gavage feeding for 3 times consecutively during 10 days without stop with a dry cotton will be used. The NNS will be performed by using the gloved small finger that stroke the palate to stimulate sucking.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Mahdiyeh Educational Hospital

Full name of responsible person
DR Maryam Khoshnud Shariyati

Street address
Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq

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2

Recruitment center

Name of recruitment center
Shohada Tajrish Educational Hospital

Full name of responsible person
DR Maryam Khoshnud Shariyati

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Tajrish Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Myself

Full name of responsible person
Zahra Khodagholi

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Shohada Tajrish Educational Hospital

City
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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
Myself

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
University of Social Welfar and Rehabilitation

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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