Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The comparison between the effect of two non-nutritive-sucking methods include emptied breast and pacifier sucking on the time needed to achieve full oral feeding in preterm infants

Protocol summary

Summary

The aim of this study is to determine the effect of non-nutritive-sucking with two methods of emptied breast and pacifier sucking on the time needed to achieve full oral feeding in preterm infants. This study is a triple blind clinical trial with simple random sampling on 78 premature infants. New born infants with gestational age between 26 to 33 weeks and birth weight less than 1500 gr and physiological stability while starting oral stimulation will enter to study. Having any congenital anomalies, chronic medical problems during or after oral stimulation program, seizure in the first 24 hours after birth, ability to natural sucking and oral feeding, infant will be excluded from the study. Infants under study will be divided randomly into three groups included: two intervention groups and one control group. Oral stimulation program will be performed using a pacifier twice a day in the first group, and using mothers' breast twice a day in the second group, for ten days consecutively. The control group in addition to receive routine nursing care infants will be received non-specialized head and face stimulates as placebo. The participants will be assessed for time to achieve full oral feed, the weight gain after a week and after 10 days of oral stimulation program and the weight gain at discharge, gestational age at the time of oral feeding and discharge.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122325673N1**
Registration date: **2016-09-26, 1395/07/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-26, 1395/07/05

Registrant information

Name
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Name of organization / entity
Isfahan university of Medical Science
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Recruitment status

Recruitment complete

Funding source

Dezful University of Medical Sciences

Expected recruitment start date

2016-07-30, 1395/05/09

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison between the effect of two non-nutritive-sucking methods include emptied breast and pacifier sucking on the time needed to achieve full oral feeding in preterm infants

Public title

Comparison between two non-nutritive-sucking methods

on the time needed to achieve full oral feeding in preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: newborn infant; birth gestational age between 26 to 33 weeks; birth weight < 1500 gr; physiological stability while starting oral stimulation, which means that oral stimulation and start feeding do not make change in the autonomic nervous system (skin color, heart rate and respiratory rate). Exclusion criteria: Congenital anomalies; chronic medical problems include bronchopulmonay dysplasia, intraventricular hemorrhage (grade 3 and 4), enterocolitis necrosis and nosocomial Infection during or after oral stimulation program; having seizure in the first 24 hours after birth; being able to natural sucking and oral feeding.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Dezful University of Medical Sciences

Street address

Dezful University of Medical Sciences, Azadegan Blv.

City

Dezful

Postal code

00986142429532

Approval date

2015-07-29, 1394/05/07

Ethics committee reference number

IR.DUMS.RES.1394.6

Health conditions studied

1

Description of health condition studied

Preterm neonate's nutritinal status

ICD-10 code

P92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

Primary outcomes

1

Description

Time needed to achieve full oral feeding

Timepoint

Seven and ten days after onset of intervention and at the time of discharge

Method of measurement

Counting the number of feedings per day

Secondary outcomes

1

Description

Weight

Timepoint

Seven and ten days after onset of intervention and at the time of discharge

Method of measurement

Model DG-110 Digital Scale

2

Description

Gestational age

Timepoint

At the time of discharge

Method of measurement

Gestational age at birthday plus the number hospitalization

3

Description

Hospitalization period

Timepoint

At the time of discharge

Method of measurement

Number of hospitalization days

Intervention groups

1

Description

In the first intervention group, non-nutritional sucking stimulation will be performed using a pacifier twice a day in the morning and in the evening while doctor start to

feed infant. The intervention will be performed for 10 consecutive days by trained expert. Oral stimulation program contains two forms of oral stimulation. Around and in mouth stimulation will be done by hand for three minutes and it will be continued sucking by use of a pacifier for two minutes.

Category
Rehabilitation

2

Description
In the second intervention group, non-nutritional stimulation will be done by use of breast twice a day in the morning and in the evening for 10 consecutive days by trained experts. Before stimulation, breast milk will be fully discharged. Also before stimulation hands will be washed with soap and water and latex gloves will be used. Oral stimulation program contains two forms of oral stimulation. Around and in mouth stimulation will be done by hand for three minutes and it will be continue by sucking breast for two minutes. Before, during and after the stimulation, the infant will be monitored by the investigator and stimulation will stop immediately observing any interruption in breathing, slow heart rate and disruption in the oxygen supply.

Category
Rehabilitation

3

Description
In the control group, infants will receive non-specialized head and face stimulation in addition to routine nursing care, as placebo.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ganjavian Hospital of Dezful

Full name of responsible person
Narges Majidipour

Street address
Opposite of Type 292 Zerehy Dezful, Road of Dezful-Andimeshk, Dezful

City
Dezful

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dezful University of Medical Sciences

Full name of responsible person
Fereidon Nirouzad

Street address
Vice chancellor of Research, Dezful University of Medical Sciences, Azadegan Blv.

City
Dezful

Grant name
1245022

Grant code / Reference number
10506

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Dezful 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
Dezful University of Medical Sciences

Full name of responsible person
Narges Majidipour

Position
Master of Nursing Neonatal Intensive Care/Memeber of faculty in Dezful University of Medical Science

Other areas of specialty/work

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Dezful University of Medical Sciences, Azadegan Blv, Dezful, khuzestan, Iran.

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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