

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison the Effect of Non Nutritive Sucking and Abdomen Massage on Feeding Tolerance and Weight Changes in premature born Infants

Protocol summary

Summary

The aim of this study comparison the effect of non nutritive sucking and abdomen massage on feeding tolerance and weight changes in premature Infants. Inclusion criteria included: chronological age infants 48 hours or less, gestational age infants 30 to 34 weeks, receiving nutrition through a tube, fifth minute Apgar score of 7 and more, lack of sever respiratory distress, no need to mechanical ventilation, birth weight 1200 grams and more, absence of congenital disease. Exclusion criteria included the following: firms that have grade 3 or 4 intraventricular hemorrhage, necrotizing enterocolitis, positive blood culture at birth, sepsis were excluded from the sample. Population is all premature infants with gestational age 34-30 weeks and in Imam Reza hospital neonatal intensive care unit at Mashhad in 1394 admitted. The sample size based on previous studies and Average Comparison Formula 60 were considered. During the study, of which 8 samples of the study were excluded, and finally 52 infant completed the study. Infants were randomly assigned to three groups: abdominal massage, non-nutritive sucking and control. In abdominal massage group, intervention for 15 minutes twice a day, in non-nutritive sucking group intervention was performed for 10 minutes three times a day. Apart from routine services nursing infants in the control group did not receive any intervention. Intervention began in 48 hours of birth and continued for 7 days.Changes weight and feeding tolerance using three criteria: the amount of residue, vomiting and distention examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110330672N1**

Registration date: **2016-11-29, 1395/09/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-29, 1395/09/09

Registrant information

Name

Saideh Marzieh Fazli

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1513

Email address

m-fazli@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Non Nutritive Sucking and Abdomen Massage on Feeding Tolerance and Weight Changes in premature born Infants

Public title

The impact of abdominal massage and nonnutritive sucking on feeding tolerance and weight in preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria (48 hours or less chronological age baby; the baby's gestational age 30 to 34 weeks; Infant feeding via a nasogastric tube be done; fifth minute Apgar score of 7 and more; The absence of severe respiratory distress; lack of need for mechanical ventilation; lack of mother's addiction; birth weight 1200 grams and more; apparently healthy baby; absence of congenital disease; the absence of signs and symptoms suggestive of infection; for example PROM more than 18 hours before birth; maternal fever and positive culture; lack of Cleft palate and cleft lip) Exclusion criteria: (Intraventricular hemorrhage grade 3 or 4 on the third day ultrasonography; diagnosis of Necrotizing enterocolitis; Reported positive blood cultures birth; lack of parental consent to continue the intervention; sepsis while studying, at least 24 hours after starting enteral feeding the baby NPO)

Age

From **1 day** old to **2 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Mashhad University of Medical Sciences

Street address

University Ave.

City

Mashhad

Postal code

Approval date

2015-08-15, 1394/05/24

Ethics committee reference number

IR.MUMS.REC.1395.337

Health conditions studied

1

Description of health condition studied

weight gain

ICD-10 code

R62.8

ICD-10 code description

Other lack of expected normal physiological development

2

Description of health condition studied

Feeding problems of newborn

ICD-10 code

P92

ICD-10 code description

Feeding problems of newborn

Primary outcomes

1

Description

weight

Timepoint

daily

Method of measurement

balance

2

Description

Feeding Tolerance

Timepoint

During the intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

nonnutritive sucking three times a day for 10 minutes in the intervention group

Category

Other

2

Description

Abdominal massage twice a day for 15 minutes in the intervention group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital.

Full name of responsible person

Saideh Marzieh Fazli

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mr. Tafaqodi

Street address

University Ave.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Saideh Marzieh Fazli

Position

Nurss/Student

Other areas of specialty/work

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Master of nursing

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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