Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Saideh Marzieh Fazli
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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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
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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.
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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
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

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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