Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of counseling on exclusive breastfeeding continuation in mothers with hospitalized preterm infant using BASNEF model

Protocol summary

Summary

Objective: This study aims at determine the effect of counseling on exclusive breastfeeding continuation in mothers with hospitalized preterm infant is designed, 2014.Exclusion criteria: Singleton pregnancy; Delivery at 37-34 weeks gestation; No abnormalities in the baby at birth. Exclusion criteria: Infant mortality for any cause during the study; infants with severe respiratory distress and infection hospital in need of Nil Per Os; Continued absence of women in training sessions. Methods: This is quasi-experimental study of two groups.The target population of this study consists of all mothers and hospitalized premature infants. Sample size of 62 patients in the intervention group and 62 patients in the control group are determined. Sampling is done by random permutation block. In order to continue exclusive breastfeeding and breastfeeding counseling intervention in preterm infants during the five sessions by the researcher, daily during hospitalization for direct instruction and individual face to face, the theoretical and practical on the steps of reproductive health service (Using the replica, pamphlets, educational compact Disk training) and incentive packages and daily goals chart will be performed. But the control group will performed routine care. Data collection tools included three questionnaires to assess knowledge of mothers about breastfeeding; Training based on structural BASNEF model, demographic characteristics, check list observation and consultation performance breastfeeding mothers, and scales weighing children's model co12000 is made in Iran.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014111013405N6**
Registration date: **2015-01-05, 1393/10/15**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-01-05, 1393/10/15

Registrant information

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of counseling on exclusive breastfeeding continuation in mothers with hospitalized preterm infant using BASNEF model

Public title

The effect of counseling on breast feeding in preterm infants

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Mother are literate; Mother prevention of adduction; Not having a mother with underlying disease and gestational diabetes and preeclampsia; Singleton pregnancy; Delivery at 37-34 weeks gestation; No abnormalities in the baby at birth. Exclusion criteria: Mother's unwillingness to cooperate; Metabolic disorders in newborns; Infant mortality for any cause during the study; infants with severe respiratory distress and infection hospital in need of Nil Per Os; Continued absence of women in training sessions; Mothers taking antidepressant drugs and psychotropic substances; The inability of the breast feeding at the discretion of the physician; Infectious disease of the breast; Unavailability of the mother at the time of completing of questionnaires test and attending breastfeeding education classes during pregnancy.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **124**
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
Ethics committee of Hamedan university of Medical Scienses
Street address
Vice Chancellor of Research and Technology, Hamedan University of Medical Sciences, Shahid Fahmideh Avenue, Hamedan
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Approval date
2014-11-25, 1393/09/04
Ethics committee reference number
16/35/9/4125/پ

Health conditions studied

1

Description of health condition studied
Relationship counseling to exclusive breastfeeding continuation in mothers with hospitalized preterm infant
ICD-10 code
p05-po6-p0
ICD-10 code description
Disorders related to length of gestation and fetal growth

Primary outcomes

1

Description
exclusive breastfeeding continuation
Timepoint
Before then once monthly until 4 months after birth
Method of measurement
Check list

Secondary outcomes

1

Description
Birth weight
Timepoint
Before then once monthly until 4 months after birth
Method of measurement
Weighing Scales babies

Intervention groups

1

Description
Intervention group: breastfeeding counseling for continued exclusive breastfeeding in preterm infants during 5 session by researcher, daily during hospitalization direct instruction and individual face to face, the practical and theoretical will be performed.
Category
Prevention

2

Description
Control group: regular and ongoing training by personnel neonatal unit and after delivery to receive.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Street address
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research the Technology, Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeed Bashiriyan
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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
Vice chancellor for Research the Technology, Hamedan 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