Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison Effect of Two Crawl and Routine Breastfeeding Methods on Breastfeeding Outcomes Early After Birth

Protocol summary

Summary

(1) Objectives: Comparison effect Crawl and Routine breastfeeding on breastfeeding behaviors in two hours after childbirth. Comparison effect Crawl and Routine breastfeeding on continuous exclusive breastfeeding. (2)Design: 60 newborn of primi or two gravida women referred to Ali-Ebn-Abitaleb hospitals' Zahedan during 2009 to 2011 years. (3) Setting and Conduct: Participants will be randomized by judgmental sampling, then will be divided to two methods (Crawl and Routine breastfeeding) by simple random allocation. (4) Participants including major eligibility criteria: Inclusion criteria: 60 women with term and singleton pregnancy, without episiotomy in temperature of birth room 23 to 25 centigrade. Exclusion criteria: previous medical disorder and smoking , use pethidine / promethazine during labor, acute complication (prolong labor, postpartum hemorrhage, meconium and distress respiration newborn. (5) Intervention: Crawl group will be inserted between breasts and abdomen of the mother;s skin immediately after birth (before any interventions) for 60 minutes until start breast Crawl without helping, and Routine group only lie between breasts and abdomen of mother's skin for 15 minutes, thus newborn wrap and close mother position and caregiver help for breastfeeding during 1 hour. During this time evaluate 6 items of expository early movement and 4 items successful breastfeeding behavior with Infant Breastfeeding Assessment Tool (IBFAT) scale and skin sense satisfaction with newborn contact with numeric scale (0-5). Also, continuous exclusive breastfeeding will be assessed during 6 month. (6)Variables main outcome measure: early six breastfeeding movement and four successful breastfeeding behavior, and skin sense satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305205169N2**
Registration date: **2013-12-27, 1392/10/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-12-27, 1392/10/06

Registrant information

Name
Shahin-Dokht Navvabi-Rigi
Name of organization / entity
Pregnancy Health Research Center, Zahedan university of medical sciences
Country
Iran (Islamic Republic of)
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+98 54 1244 1259
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Zahedan University Of Medical Sciences

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Effect of Two Crawl and Routine Breastfeeding Methods on Breastfeeding Outcomes Early After Birth

Public title
Effect of Crawl method on breastfeeding
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: primi /two gravida with term and singleton pregnancy and do not episiotomy,Body Mass Index (BMI)<29. Exclusion criteria: previous medical disorder and smoking , used pethidine / promethazine during labor, acute complication (prolong labor, postpartum hemorrhage, meconium and distress respiration newborn.
Age
To **6 years** old
Gender
Both

Phase
1-2
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
type of randomization is simple.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Zahedan University Of Medical Sciences
Street address
Dr Hesabi Sq. Pardis Of Zahedan University Of Medical Sciences
City
Zahedan
Postal code
Approval date
2010-03-08, 1388/12/17
Ethics committee reference number
883192

Health conditions studied

1

Description of health condition studied
Promoting breastfeeding
ICD-10 code
Z39.0
ICD-10 code description
Care and examination immediately after delivery

Primary outcomes

1

Description
Successful breastfeeding behaviour
Timepoint
during 2 hour after birth
Method of measurement
Infant Breastfeeding Assessment Tool (IBFAT)

Secondary outcomes

1

Description
Exclusive breastfeeding
Timepoint
4th after intervention and 6th after intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
Crawl group: Immediately after birth, in first step skin newborn will dry (except hands), next face to face and smell will contact near mother during 1 minute, end step immediately skin to skin will contact between abdomen and breasts during 1 hour and will wait for observation Crawl forward nipple.
Category
Behavior

2

Description
Control group (Routine group): Immediately after birth, newborn dry, next will contact skin mother's during 15 minute, and will wrap towel and lied near mother nipple and end step will observe during 1 hour.
Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali-Ebn-Abitaleb hospital

Full name of responsible person

Street address

City
Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Zahedan University Of Medical Sciences

Full name of responsible person
Sodabeh Hashemzehi

Street address
Dr Hesabi sq.Pardis Zahedan University Of Medical Sciences

City
Zahedan

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, Zahedan 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
Pregnancy Health Research Center, Zahedan University Of Medical Sciences

Full name of responsible person
Shahin-Dokht Navvabi-Rigi

Position
Faculty of mastery

Other areas of specialty/work

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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