

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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; 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)

Phone

+98 54 1244 1259

Email address

navabi-rigi@zaums.ac.ir

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