

# 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**

**Street address**

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**Position**

faculty mastery of midwifery

**Other areas of specialty/work**

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**Position**

mastery of Midwifery

**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*