

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of midwife's supportive care during labor on onset of lactogenesisII and exclusive breastfeeding

Protocol summary

Summary

This study aims to determine the effect of midwife's supportive care during labour on onset of lactogenesisII and exclusive breastfeeding. In a randomized clinical trial study, 80 primigravida women in Omolbanin Hospital in Mashhad will be recruited. The inclusion criteria for subjects are: gestational age 38-42 weeks, single foetus and live with cephalic presentation, cervical dilation 3-4 cm, no medical and obstetric complications and no evidence of fetal distress. Subjects will be allocated randomly into supportive care and usual care groups. Women with medical complications and congenital malformations in infant will be excluded. Experimental group will receive supportive care including physical, educational and emotional support during active phase of labour and also the first hours after delivery by the researcher. Control group will receive usual labour and delivery care by staff midwives. Labour progress and breastfeeding status will be monitored and recorded by the researcher in both groups. In both groups appearance of clinical symptoms of lactogenesisII (mother reports milk leaking) will be determined through daily phone contacts during postpartum period. In addition mothers will be asked to fill a daily checklist about infants feeding from birth until the sixth weeks following delivery. The onset of lactogenesis II and frequency of exclusive breastfeeding at the end of four and six weeks will be compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810122956N1**

Registration date: **2010-05-25, 1389/03/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-25, 1389/03/04

Registrant information

Name

Masoumeh Kordi

Name of organization / entity

Nursing and Midwifery School, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1859 1511

Email address

kordim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2008-09-11, 1387/06/21

Expected recruitment end date

2009-04-08, 1388/01/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of midwife's supportive care during labor on onset of lactogenesisII and exclusive breastfeeding

Public title

Midwife's supportive care and breastfeeding

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: primigravida women, gestational age 38-42 weeks, single foetus, live with cephalic presentation, cervical dilation 3-4 cm, no medical and obstetric complications and no evidence of foetal distress. Exclusion criteria: Medical complications and congenital malformations in infant

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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 Mashhad University of Medical Sciences

Street address

Ghoreishi building, Daneshgah ave, Mashhad, Iran

City

Mashhad

Postal code

91375345

Approval date

empty

Ethics committee reference number

86367

Health conditions studied**1****Description of health condition studied**

Neonatal difficulty in feeding at breast

ICD-10 code

P92.5

ICD-10 code description

Neonatal difficulty in feeding at breast

Primary outcomes**1****Description**

Onset of lactogenesisII

Timepoint

One weekes after birth

Method of measurement

Questionnaire, checklist

Secondary outcomes**1****Description**

Exclusive breastfeeding

Timepoint

Six weekes after birth

Method of measurement

Cheklist of daily newborn feeding record

Intervention groups**1****Description**

Experimental group will receive supportive care including physical, educational and emotional support during active phase of labor and also the first hours after delivery by the researcher

Category

Prevention

2**Description**

Control group will receive usual labor and delivery care by staff midwives

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Omolbanin Hospital in Mashhad

Full name of responsible person

Massomeh kordi

Street address

Mashhad Faculty of Nursing and Midwifery, Ebne sina St., Chaharah Doktora Crossing

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

<http://www.mums.ac.ir/research>

Street address

Ghoreishi building, Daneshgah Ave., Mashhad-Iran

City

Mashhad

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

Contact**Name of organization / entity**

Mashhad Faculty of Nursing and Midwifery

Full name of responsible person

Massomeh Kordi

Position

M.Sc. of Midwifery

Other areas of specialty/work**Street address**

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Person responsible for scientific 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