Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Schoo, 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
Mashhad Faculty of Nursing and Midwifery, Ebne sina St., Chaharah Doktora Crossing
City
Mashhad
Postal code
9137913199
Phone
+98 51 1859 1511
Fax
+98 51 1859 7313
Email
kordim@mums.ac.ir
Web page address
www.mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing and Midwifery
Full name of responsible person
Massomeh Kordi
Position
M.Sc. of Midwifery
Other areas of specialty/work
Street address
Mashhad Faculty of Nursing and Midwifery, Ebne sina St., Chaharah Doktora Crossing
City
Mashhad
Postal code
9137913199
Phone
+98 51 1859 1511
Fax
0O985118597313
Email
kordim@mums.ac.ir
Web page address
www.mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Faculty of Nursing and Mdwifery
Full name of responsible person
Massomeh Kordi
Position
M.Sc. of Midwifery
Other areas of specialty/work
Street address
Mashhad Faculty of Nursing and Midwifery, Ebne sina St., Chaharah Doktora Crossing
City
Mashhad
Postal code
9137913199
Phone
+98 51 1859 1511
Fax
+98 51 1859 7313
Email
kordim@mums.ac.ir
Web page address
www.mums.ac.ir

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