

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Evaluation the effect of continuous midwifery care model during pregnancy, labor and postpartum on maternal and neonatal

Protocol summary

Summary

This study is a randomized clinical trial. The sample population is pregnant women in Kashan city. One hundred women will be under continuous care model (case group) and one hundred women will be received routine care (control group). The subjects will be recruited by random multistage method. The Kashan city will be divided according to the comprehensive health centers. Seven centers will be selected randomly. The sample size of every area will be calculated according to the population coverage of the centers. The eligible samples will be appointed randomly. The control and case group will be matched according to the number of pregnancies, birth, age, education, occupation, economic status and residency. The data will be gathered using questionnaire, interview form and check list. Maternal and neonatal outcomes and maternal satisfaction will be compared in two groups using SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408318801N9**

Registration date: **2016-08-15, 1395/05/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-15, 1395/05/25

Registrant information

Name

Masoumeh Simbar

Name of organization / entity

Shahid Beheshti University for Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 2517

Email address

msimbar@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University Of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of continuous midwifery care model during pregnancy, labor and postpartum on maternal and neonatal

Public title

Development and evaluating a model of continuous midwifery care during pregnancy, labor and postpartum, an action research study

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: The Low risk pregnant women that: - Their gestational age is under fourteen weeks - They have not any diseases - They have not previous high risk pregnancy - They have not history for infertility - They have not previous cesarean section - They have not previous abdominal surgery Exclusion criteria: - Their pregnancy be high risk - They have no desire to continue staying in the study

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: **200**

Randomization (investigator's opinion)

Not 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 Kashan University of Medical Sciences

Street address

Nurse street, Ravand High Way

City

Kashan

Postal code

8715587111

Approval date

2014-10-11, 1393/07/19

Ethics committee reference number

29/5/1/3312/پ

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

pregnancy

ICD-10 code

000-099

ICD-10 code description

Supervision of normal pregnancy, unspecified

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

maternal satisfaction

Timepoint

1 month after intervention

Method of measurement

Questionnaire

2**Description**

maternal outcomes

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

3**Description**

neonatal outcomes

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

4**Description**

number of visits in pregnancy

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

5**Description**

number of sonography

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

6**Description**

fetal death before or after 24 weeks

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

7**Description**

hospitalization

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

8**Description**

bleeding before delivery

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

9**Description**

husband presence in visits

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

10**Description**

induction

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

11**Description**

physiologic delivery

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

12**Description**

analgesic and anesthesia

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

13**Description**

duration of labor

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

14**Description**

duration of hospitalization

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

15**Description**

delivery type

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

16**Description**

episiotomy

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

17**Description**

perineal laceration

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

18**Description**

gestational age at the termination

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

19**Description**

neonatal weight

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

20**Description**

preterm neonate

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

21**Description**

5th minute Apgar score

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder

22**Description**

NICU hospitalization

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

23**Description**

depression after delivery

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and interview

24**Description**

breast feeding onset

Timepoint

at the end of intervention

Method of measurement

interview

25**Description**

continuous pain after delivery

Timepoint

at the end of intervention

Method of measurement

interview

26**Description**

expenditure

Timepoint

at the end of intervention

Method of measurement

observe the hospital folder and calculation

Secondary outcomes

empty

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

The intervention in case group includes: Hiring a responsible midwife for every pregnant woman. This midwife is a member of management team and provides direct care during prenatal, delivery and postpartum stages. If pregnant women need special care, the midwife will refer her to the specialist and will take feedback. Responsible midwife will continuously be available for pregnant women in different settings of home, health centers and hospital.

Category

Other

2**Description**

The control group will receive routine care. In routine method, pregnant women refer to health center. There is not responsible midwife or continuous relationship with care provider. Most of women are under supervision of specialist no matter, they are high or low risk. Care providers change repeatedly during prenatal, delivery and postpartum stages. Care provider may be unknown for women.

Category

Other

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

Shabih Khani Hospital

Full name of responsible person

Fatemeh Rezvanitabar

Street address

Shahid Beheshti Street, Kashan

City

Kashan

2**Recruitment center****Name of recruitment center**

Golabchi health center

Full name of responsible person

Fatemeh Nazarneia

Street address

Emam street, Kashan

City

Kashan

3**Recruitment center****Name of recruitment center**

Moslem health center

Full name of responsible person

Maliheh Sarvizadeh

Street address

Rajae Street, Kashan

City

Kashan

4**Recruitment center****Name of recruitment center**

Emam Ali health center

Full name of responsible person

Fatemeh Rafee

Street address

Nagiabad street, Kashan

City

Kashan

5

Recruitment center

Name of recruitment center

Sadeghpour health center

Full name of responsible person

Maryam Javani

Street address

Emam Javad street, Kashan

City

Kashan

6

Recruitment center

Name of recruitment center

Karegar health center

Full name of responsible person

Zohreh Rabbani

Street address

Karegar street, Kashan

City

Kashan

7

Recruitment center

Name of recruitment center

Matini health center

Full name of responsible person

Zahra Zare

Street address

Amir Kabir Street, Kashan

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

velenjak

City

Tehran

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, Shahid Beheshti 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

Kashan University of Medical Sciences

Full name of responsible person

Azam Bagheri

Position

Trainee

Other areas of specialty/work

Street address

Nurse Street, Ravand High Way

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Phone

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Fax

Email

asambagheri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoumeh Simbar

Position

Associate Professor

Other areas of specialty/work

Street address

Crossing Vali-Asr Neiayesh

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Tehran

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Fax

Email

msimbar@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Azam Bagheri

Position

Trainee

Other areas of specialty/work

Street address

Midwifery Group, School of nursing and midwifery,
Nurse Street, Ravand High Way, Kashan

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asambagheri@yahoo.com

Web page address**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