

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Presenting a Pattern of Postpartum Care at Home and Its Effects on the Health of the Mother and the Suckling

#### Protocol summary

##### Summary

Objective: Presenting a pattern of postpartum care at home and its effects on the health of the mother and suckling. Method: This interventional study is a randomized trial. First, we reach a unique pattern by summarizing data from the study of the pattern of postpartum care at home in different countries. Then by gathering journalists' and stakeholders' comments there will be changes in accordance with the needs of the country. The study population is woman who have given birth in Shohada, Imam Hossein, Taleqani and Mahdieh hospitals. After obtaining consent, 270 eligible mothers are elected successively, we allocate 90 people in intervention group and 180 people in control group. Inclusion criteria: Iranian nationality; no gestational hypertension and Diabetes; single embryo with normal birth weight; having a score less than 14 in Edinburg questionnaire. Exclusion criteria: unwillingness to continue the study for any reason; immigration from the areas of study. The type of intervention for both groups is providing service in accordance with the approved pattern at home and to visit in days of 3-5 and 13-15 after the delivery. The control group won't be provided with home service. The review of the results will be conducted on days 42-60 and mother and suckling health indices between two groups will be compared. These indices include using supplementation by mother and suckling, postpartum depression, mother hospitalization due to the complications after childbirth, exclusive feeding with breast milk, infant hospitalization after the first 28 days of childbirth and common physical complications in mothers in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013060313565N1**

Registration date: **2013-12-07, 1392/09/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-12-07, 1392/09/16

##### Registrant information

###### Name

Parastoo Amiri

###### Name of organization / entity

Shaheed Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2220 2563

###### Email address

amiri.parasto@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Shaheed Beheshti University of Medical Sciences

##### Expected recruitment start date

2013-10-23, 1392/08/01

##### Expected recruitment end date

2014-01-05, 1392/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Presenting a Pattern of Postpartum Care at Home and Its Effects on the Health of the Mother and the Suckling

##### Public title

Effects of Postpartum Care at Home on the Health of the

Mother and Suckling

### **Purpose**

Health service research

### **Inclusion/Exclusion criteria**

Inclusion criteria: Iranian nationality; no gestational hypertension, preeclampsia and gestational diabetes; single embryo with normal birth weight; no congenital anomalies; having a score less than 14 in Edinburg questionnaire. Exclusion criteria: unwillingness to continue the study for any reason; immigration from the areas of study

### **Age**

From **15 years** old to **45 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **270**

### **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**

Shaheed Beheshti University of Medical Sciences

##### **Street address**

Velenjak , Shahid Chamran Highway

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2012-11-11, 1391/08/21

#### **Ethics committee reference number**

0308/11470

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Postpartum Period

#### **ICD-10 code**

Z39.1, Z39

### **ICD-10 code description**

Care and examination of lactating mother, Routine postpartum follow-up

## **Primary outcomes**

### **1**

#### **Description**

Using supplementation in mother in intervention and control groups

#### **Timepoint**

42-60 days after intervention

#### **Method of measurement**

questionarie

### **2**

#### **Description**

Using supplementation in suckling in intervention and control groups

#### **Timepoint**

42-60 days after intervention

#### **Method of measurement**

questionarie

### **3**

#### **Description**

Using the contraceptive methods in intervention and control groups

#### **Timepoint**

42-60 days after intervention

#### **Method of measurement**

questionarie

### **4**

#### **Description**

Incidence of Postpartum depression in intervention and control groups

#### **Timepoint**

42-60 days after intervention

#### **Method of measurement**

Edinburg questionarie

### **5**

#### **Description**

Mother hospitalization due to complications after childbirth in intervention and control groups

#### **Timepoint**

42-60 days after intervention

#### **Method of measurement**

questionarie

### **6**

#### **Description**

Exclusive feeding with breast milk in intervention and control groups

#### **Timepoint**

42-60 days after intervention

**Method of measurement**

questionnaire

**7**

**Description**

Breast problems in intervention and control groups

**Timepoint**

42-60 days after intervention

**Method of measurement**

questionnaire

**8**

**Description**

Constipation in intervention and control groups

**Timepoint**

42-60 days after intervention

**Method of measurement**

questionnaire

**9**

**Description**

Hemorrhoids in intervention and control groups

**Timepoint**

42-60 days after intervention

**Method of measurement**

questionnaire

**10**

**Description**

Backache and lumbago in intervention and control groups

**Timepoint**

42-60 days after intervention

**Method of measurement**

questionnaire

**11**

**Description**

Fatigue in intervention and control groups

**Timepoint**

42-60 days after intervention

**Method of measurement**

questionnaire

**Secondary outcomes**

**1**

**Description**

Satisfaction rate in intervention and control groups

**Timepoint**

42-60 days after intervention

**Method of measurement**

questionnaires

**Intervention groups**

**1**

**Description**

The type of intervention for both groups is providing service in accordance with the approved pattern at home and to visit in days of 3-5 and 13-15 after the delivery. Visits are done by trained midwives or nurses. The average time of visit is considered between 30-45 minutes, which is flexible according to mothers' demands. The service provider's phone number is given to mothers in case of any problems. Caregivers will be trained before the intervention, so there will be integration in the caring method.

**Category**

Prevention

**2**

**Description**

The control group won't be provided with home service.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Mahdie Hospital

**Full name of responsible person**

Dr. Mehrdad Izadi , Hospital administration

**Street address**

Shoosh ".Sq." ,Fadaeian Eslam".Av."

**City**

Tehran

**2**

**Recruitment center**

**Name of recruitment center**

Emam Hossein Hospital

**Full name of responsible person**

Dr.seid Mohammad Taghi Hosseini Tabatabae, Hospital administration

**Street address**

Tehran, Shaheed Madani Avenue

**City**

Tehran

**3**

**Recruitment center**

**Name of recruitment center**

Taleghani Hospital

**Full name of responsible person**

Dr. Abbas Haj Fathali , Hospital administration

**Street address**

Velenjak, shahid chamran highway

**City**

Tehran

#### 4

##### **Recruitment center**

###### **Name of recruitment center**

Shohada Hospital

###### **Full name of responsible person**

Dr.Badiozaman Radpey, Hospital administration

###### **Street address**

Tajrish, Qods ".Sq."

###### **City**

Tehran

#### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Vice chancellor for research, Shaheed Beheshti  
University of Medical Sciences

###### **Full name of responsible person**

Dr.Hossein Goodarzi

###### **Street address**

Velenjak, Shahid Chamran Highway

###### **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, Shaheed 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**

Shaheed Beheshti university of Medical Sciences

###### **Full name of responsible person**

Parastoo Amiri

###### **Position**

Resident of Community medicine

###### **Other areas of specialty/work**

###### **Street address**

Velenjak,Shaheed Beheshti Faculty of  
medicine,Eighth floor,Public health & Community  
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###### **Phone**

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###### **Fax**

###### **Email**

Amiri.Parasto@gmail.com ;

Amiri\_Parasto@yahoo.com

###### **Web page address**

#### **Person responsible for scientific inquiries**

##### **Contact**

###### **Name of organization / entity**

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###### **Full name of responsible person**

Dr.Hourieh Shamshiri Milani

###### **Position**

assistant professor

###### **Other areas of specialty/work**

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###### **Web page address**

#### **Person responsible for updating data**

##### **Contact**

###### **Name of organization / entity**

Shaheed Beheshti University of Medical Sciences

###### **Full name of responsible person**

Parastoo Amiri

###### **Position**

Resident Of Community Medicine

###### **Other areas of specialty/work**

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###### **Fax**

###### **Email**

Amiri.Parasto@gmail.com ;

Amiri\_Parasto@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*