

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of physiological birth on mother and newborn health

#### Protocol summary

##### Summary

Objective: We aimed to determine the effect of physiological birth in outcomes of delivery, including duration of first, second and third stages of labour, amount of blood loss in the third and fourth stages of labour, perineal statue, delivery method, decolman, asphyxia, apgar score and satisfaction of birth. Methods: A randomised controlled trial was completed on 200 women who gave birth at Akbar Abadi hospital in Tehran, Iran. 100 were allocated to physiological birth (intervention group) and 100 to routine vaginal birth (control group). Inclusion criteria included the following: gestational age between 37 and 42 weeks; singleton pregnancy; live fetus; cephalic presentation; neonatal birth weight estimation of 2500–4000 g; maternal age 18-45 years; and vaginal dilatation between 3 and 4 centimeter. The data collection instruments included three questionnaires.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138805062248N1**

Registration date: **2010-08-30, 1389/06/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-08-30, 1389/06/08

##### Registrant information

##### Name

Fereshteh Jahdi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

00982188773073,00982182471404

##### Email address

f.jahdi@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Iran University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2009-07-29, 1388/05/07

##### Expected recruitment end date

2010-03-27, 1389/01/07

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of physiological birth on mother and newborn health

##### Public title

The effect of physiological bith on mother and newborn health

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria included the following: 1- gestational age between 37 and 42 weeks 2- singleton pregnancy 3- live fetus 4- cephalic presentation; neonatal birth 5- weight estimation of fetus : 2500–4000 g 6- maternal age 18-45 years 7- vaginal birth. Exclusion criteria included the following: 1- Blood pressure <140/90mmHg 2- Placenta previa 3- A history of caesarean section or any uterine scar 4- Polyhydramnios 5- Prolonged rupture of membranes

##### Age

From **18 years** old to **45 years** old

##### Gender

Female

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: **200**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

School of nursing and midwifery, Iran University of Medical Sciences

**Street address**

Valiasr Ave. Rashidyasemi Ave.

**City**

Tehran

**Postal code**

**Approval date**

2009-07-20, 1388/04/29

**Ethics committee reference number**

1323583

**Health conditions studied**

1

**Description of health condition studied**

Physiological Birth

**ICD-10 code**

O00-O99

**ICD-10 code description**

Pregnancy, childbirth and the puerperium

**Primary outcomes**

1

**Description**

Duration of the first stage of labor

**Timepoint**

cervix dilatation from 4 centimeter to 10 centimeter

**Method of measurement**

Digital chronometer

2

**Description**

Duration of the second stage of labor

**Timepoint**

Cervix dilatation from 10 centimeter to fetus expulsion

**Method of measurement**

Digital chronometer

3

**Description**

Duration of the third stage of labor

**Timepoint**

From completed delivery of the fetus to completed delivery of the placenta

**Method of measurement**

Digital chronometer

4

**Description**

The amount of blood loss during the third stage of labour

**Timepoint**

Third stage of labour

**Method of measurement**

Scaled dish

5

**Description**

The amount of blood loss during the third stage of labour

**Timepoint**

Third stage of labour

**Method of measurement**

Scaled dish

6

**Description**

The amount of blood loss during the forth stage of labour

**Timepoint**

Forth stage of labour

**Method of measurement**

Scaled dish

**Secondary outcomes**

1

**Description**

Decolman

**Timepoint**

First stage of labor

**Method of measurement**

Obsevation and record in questionnaire

2

**Description**

Asphyxia

### **Timepoint**

First and second stage of labor

### **Method of measurement**

Obsevation and record in questionnaire

### **3**

#### **Description**

Perineal statue

#### **Timepoint**

After delivery of placenta

#### **Method of measurement**

Obsevation and record in questionnair

### **4**

#### **Description**

Method of delivery

#### **Timepoint**

After delivery of fetus

#### **Method of measurement**

Obsevation and record in questionnair

### **5**

#### **Description**

Apgar score

#### **Timepoint**

1 and 5 minute

#### **Method of measurement**

Obsevation and record in questionnaire

### **6**

#### **Description**

Satisfaction of delivery

#### **Timepoint**

Before discharging of hospital

#### **Method of measurement**

Macky satisfaction questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intevention: physiological birth

#### **Category**

Prevention

### **2**

#### **Description**

Control group: Rutine normal delivery

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

**Name of recruitment center**

Akbar Abaadi hospital

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

Maryam Shahnazari Avval

#### **Street address**

Molavi street

#### **City**

Tehran

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Iran University of Medical Sciences, vice chancellor for research

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

Dr. Motevalian

##### **Street address**

Hemmat High way

##### **City**

Tehran

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Iran University of Medical Sciences, vice chancellor for research

#### **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**

Iran University of Medical Sciences, School of Nursing and Midwifery

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

Maryam shahnazari Avval

##### **Position**

Master in midwifery

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

##### **Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences, School of Nursing and Midwifery

**Full name of responsible person**

Maryam shahnazari Avval

**Position**

Master in Midwifery

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

Valiasr Ave. Rashidiasemi Ave.

**City**

Tehran

**Postal code****Phone**

+98 26 1445 1433

**Fax****Person responsible for updating data****Contact****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*