

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effectiveness of implementation of evidence based clinical practices on mother and newborn outcomes during normal labor and delivery

#### Protocol summary

##### Summary

A single-blind, randomized controlled clinical trial will be conducted between May and September 2014 at Shahid Beheshti hospital, affiliated to Isfahan University of Medical Sciences, Isfahan, Iran. This study was approved by the ethics committee at the Isfahan University of Medical Sciences. The aim of this study is to compare the effect of «evidence based care» with «routine care » on mother and newborn outcomes during normal labor and delivery. Two hundred low risk pregnant women aged 18-35 years will be randomly allocated to receive either «evidence based care» or «routine care». One hundred were allocated to intervention group and 100 to control group. The main outcome of the study including duration of active phase and second stage of labor, labor Pain intensity, frequency use of oxytocin during normal labor, frequency use of routine episiotomy, postpartum hemorrhage, spontaneous tears in perinea and vagina, method of delivery, average time of admission to discharge, mother's satisfaction of delivery, newborns Apgar score, frequency newborns admission to neonatal ward or NICU, breast feeding during 30 minute after birth.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014050411360N1**  
Registration date: **2014-05-11, 1393/02/21**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-05-11, 1393/02/21

##### Registrant information

##### Name

Mina Iravani

##### Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 916 322 2899

##### Email address

iravani-m@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2014-05-10, 1393/02/20

##### Expected recruitment end date

2014-09-21, 1393/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness of implementation of evidence based clinical practices on mother and newborn outcomes during normal labor and delivery

##### Public title

Evidence Based Labor and Normal Delivery Management: A Mixed Methods Study

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: intend to participation in study; low risk pregnant women; maternal age 18-35 years old; single pregnancy; gestational age 38-42 weeks; vertex presentation; spontaneous labor pain; vaginal dilatation

between 3 and 4 centimeter; mother BMI 19.8-26 kg/m<sup>2</sup>; estimated fetal weight 2500-4000 gr. Exclusion criterion: unwillingness or reject of participation in study

#### **Age**

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

Ethics Committee of the Isfahan University of Medical Sciences

##### **Street address**

Research Dupty of Isfahan University of Medical Sciences, Hezarjereeb Street, Isfahan, Iran.

##### **City**

Isfahan

##### **Postal code**

8174673461

#### **Approval date**

2012-08-12, 1391/05/22

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

391206

## **Health conditions studied**

### 1

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

Delivery

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

O80

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

Single spontaneous delivery

## **Primary outcomes**

### 1

#### **Description**

Duration of active phase and second stage of labor

#### **Timepoint**

Cervix dilatation from 4 centimeter to 10 centimeter for active phase of labor and cervix dilatation from 10 centimeter to delivery of newborn for second stage of labor

#### **Method of measurement**

Clinical examination/ Measurement by digital chronometer / record in check list

### 2

#### **Description**

Labor Pain intensity

#### **Timepoint**

Measurement severity of pain during first and second stage of labor

#### **Method of measurement**

By visual analog scale/ record in check list

### 3

#### **Description**

Frequency use of oxytocin during normal labor

#### **Timepoint**

During first and second stage of normal labor

#### **Method of measurement**

Observation / record in check list

### 4

#### **Description**

Frequency use of routine episiotomy

#### **Timepoint**

Before of delivery

#### **Method of measurement**

Observation and record in check list

### 5

#### **Description**

Post partum hemorrhage

#### **Timepoint**

After childbirth

#### **Method of measurement**

Measurement of HG and HCT level by blood sampling 12 and 24 h after childbirth

### 6

#### **Description**

Spontaneous tears in perinea and vagina

#### **Timepoint**

After of delivery

#### **Method of measurement**

Observation / clinical examination/ record in check list

## 7

### **Description**

Method of delivery

### **Timepoint**

After of delivery

### **Method of measurement**

Observation and record in check list

## 8

### **Description**

Mother's satisfaction of delivery

### **Timepoint**

Before discharging of hospital

### **Method of measurement**

Macky satisfaction questionnaire

## 9

### **Description**

Apgar score

### **Timepoint**

1 and 5 minute after of delivery

### **Method of measurement**

Observation and record in check list

## 10

### **Description**

Frequency newborn admission to neonatal ward or NICU

### **Timepoint**

After of delivery

### **Method of measurement**

Observation and record in check list

## 11

### **Description**

Breast feeding during 30 min after birth

### **Timepoint**

during 30 min after birth

### **Method of measurement**

Observation and record in check list

## 12

### **Description**

Average time of admission to discharge of mother

### **Timepoint**

Of admission time to discharge

### **Method of measurement**

Measurement by Digital chronometer / record in check list

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: The subjects in this group will receive evidence based care during normal labor and delivery

#### **Category**

Other

### 2

#### **Description**

Control group: This group will be received routine care of hospital during normal labor and delivery

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Beheshti Medical and Training Hospital of Isfahan  
University of Medical Sciences

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

Mrs. Mina Iravani and Dr. Elahe Zarean

##### **Street address**

Beheshti Hospital of Isfahan University of Medical  
Sciences, Pol Felezi- Motaheri Street, Isfahan, Iran

##### **City**

Isfahan

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Isfahan University of Medical Sciences

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

Dr Peyman Adibi

##### **Street address**

Research Dupty of Isfahan University of Medical  
Sciences, Hezarjereeb Street, Isfahan, Iran

##### **City**

Isfahan

##### **Grant name**

فصل دوم برنامه تحقیقات دانشجویی

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

10506-1191

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

Yes

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

Isfahan 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

Isfahan University of Medical Sciences, Nursing and Midwifery School

#### Full name of responsible person

Mina Iravani

#### Position

PhD candidate in Reproductive Health

#### Other areas of specialty/work

#### Street address

Faculty of nursing and midwifery, Isfahan University of Medical Sciences, Iran

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#### Web page address

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences, Isfahan, Iran

#### Full name of responsible person

Mina Iravani, Dr. Elahe Zarean, Dr. Mohsen Janghorbani

#### Position

PhD candidate in Reproductive Health; Assistant Professor-Fellowship in Prinatology; Professor in Ep

#### Other areas of specialty/work

#### Street address

Department of Midwifery and Reproductive Health, School of Nursing and Midwifery, Isfahan University of Medical Sciences, Isfahan, Iran. Department of Obstetrics and Gynecology, School of Medicine, Isfahan University of Medical Sciences, Isfahan, Iran. Department of Epidemiology, School of Public Health, Isfahan University of Medical Sciences, Isfahan, Iran.

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#### Web page address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Isfahan University of Medical Sciences, Nursing and Midwifery School

#### Full name of responsible person

Mina Iravani

#### Position

PhD candidate in Reproductive Health

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Faculty of nursing and midwifery- Isfahan University of Medical Sciences, Isfahan, Iran

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#### Email

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#### Web page address

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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