

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The impact of a computerized decision aid on empowering pregnant women for choosing vaginal versus cesarean section delivery

#### Protocol summary

##### Summary

The main objective of this study is to evaluate the effect of a computerized decision aid (CDA) system on empowering pregnant women in choosing an appropriate mode of delivery. This CDA contrasts the advantages and disadvantages of vaginal versus cesarean section delivery in terms of their value to the individual woman. The CDA provides educational contents as well as some recommendations. The CDA's software will be installed on women's computer to be used at home. The protocol concerns a randomized trial study that will be performed among Iranian women. Four hundred pregnant women will be recruited from two private and two public prenatal centers in Mashhad, Iran. They will be randomly assigned in either an intervention or control group. The designed CDA will be provided to the intervention group whereas the control group will only receive routine care. Because the study is not blinded we use blocked randomization to ensure equal group sizes within each. Pregnant women 16 years and older who had 28 or more weeks of gestation are eligible to be enrolled in the study. Women are excluded if they unable to read and write or unable to work with a computer. The two primary outcomes for the study are O'Connor's decisional conflict scale and knowledge as measured by true/false questions. The duration of the intervention is considered from recruitment to the time of delivery. After intervention evaluation will be taken at 38 weeks of gestation.

#### General information

##### Acronym

CDAs

##### IRCT registration information

IRCT registration number: **IRCT2015093010777N4**

Registration date: **2015-10-26, 1394/08/04**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-10-26, 1394/08/04

##### Registrant information

###### Name

Azam Aslani Mamghani

###### Name of organization / entity

Mashhad University of medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1894 2657

###### Email address

aslania881@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences, Vice chancellor for research

##### Expected recruitment start date

2016-04-10, 1395/01/22

##### Expected recruitment end date

2017-04-30, 1396/02/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The impact of a computerized decision aid on empowering pregnant women for choosing vaginal versus cesarean section delivery

##### Public title

computerized patient decision aid system

##### Purpose

Supportive

### **Inclusion/Exclusion criteria**

Inclusion criteria: Pregnant women 16 years and older; gestational age 28 week or more; singleton pregnancy.  
Exclusion criteria: Women do not provide a written informed consent; unable to read and write; unable to work with a computer; women whose method of delivery is predetermined by the physician, based on their clinical condition

### **Age**

From **16 years** old to **48 years** old

### **Gender**

Female

### **Phase**

3

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

*No information*

### **Sample size**

Target sample size: **400**

### **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 Biomedical research, Mashhad  
University of Medical Sciences- IR.MUMS.REC

##### **Street address**

Ghoreishi building Daneshgah street

##### **City**

Mashhad

##### **Postal code**

۳۴۵ - ۹۱۳۷۵

#### **Approval date**

2015-09-15, 1394/06/24

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

IR.MUMS.REC.1391.801

## **Health conditions studied**

### 1

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

Delivery

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

O80.9

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

Single spontaneous delivery, unspecified

## **Primary outcomes**

### 1

#### **Description**

Decisional Conflict

#### **Timepoint**

Before the intervention and 4 till 10 weeks after of the intervention

#### **Method of measurement**

O'Connor's decisional conflict scale - University of Ottawa

### 2

#### **Description**

knowledge

#### **Timepoint**

Before the intervention and 4 till 10 weeks after of the intervention

#### **Method of measurement**

true/false questions

## **Secondary outcomes**

### 1

#### **Description**

Decisional Conflict subscales

#### **Timepoint**

Before and after of the intervention

#### **Method of measurement**

O'Connor's decisional conflict scale - University of Ottawa

## **Intervention groups**

### 1

#### **Description**

Intervention group will receive a computer based decision aids on mode of delivery in addition to conventional care .

#### **Category**

Other

### 2

#### **Description**

Control group will receive the conventional care.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

Public health centers

**Full name of responsible person**

Fatemeh Tara

**Street address**

16 Ayatollah Behjat street Zarine Intersection

**City**

Mashhad

**2**

**Recruitment center**

**Name of recruitment center**

private offices

**Full name of responsible person**

Azam Aslani

**Street address**

Department of Medical Informatics School of medicine, Pardis university campus, Park square

**City**

Mashhad

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences, Vice chancellor for research

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Ghoreishi building, Daneshgah street

**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, 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**

Mashhad University of Medical Sciences, Vice chancellor for research

**Full name of responsible person**

Mohsen Tafaghodi

**Position**

Vicar of research

**Other areas of specialty/work**

**Street address**

Ghoreishi building, Daneshgah street

**City**

Mashhad

**Postal code**

91775-1365

**Phone**

+98 51 3882 3251

**Fax**

**Email**

tafaghodim@mums.ac.ir

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Science

**Full name of responsible person**

Saeid Eslami

**Position**

Pharm.D.; Ph.D

**Other areas of specialty/work**

**Street address**

Department of Medical Informatics, school of medicine, Pardis university campus, Park square

**City**

Mashhad

**Postal code**

**Phone**

+98 51 3800 2429

**Fax**

**Email**

eslams@mums.ac.ir

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Science

**Full name of responsible person**

Azam Aslani

**Position**

PhD of medical informatics

**Other areas of specialty/work**

**Street address**

Department of Medical Informatics, school of medicine, Pardis university campus, Park square

**City**

Mashhad

**Postal code**

**Phone**

+98 21814524214

**Fax**

**Email**

azamaslani@yahoo.com

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*