

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