

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The impact of a computerized decision aids on the mode of delivery, compared with the conventional care

Protocol summary

Summary

The objective of the project is to evaluate a decision aid system (DAs) on mode of delivery. This computerized DA will help pregnant women in making decision about the mode of delivery, by clarifying the advantages and disadvantages of cesarean delivery without medical reason. 60 healthy pregnant women are recruited from two private and two public prenatal centers in Mashhad, they will be assigned in either an intervention or control group. The intervention group will receive the mode of delivery DAs and the control group will receive the conventional care. The system body of knowledge is extracted from the studies on the predictors of cesarean delivery. The DAs will ask a series of questions and offers appropriate advice based on women's answers. Another part of the system is education. The DAs will be installed on women PCs so they enable to use it frequently at home. The two primary outcomes for the study are decisional conflict, and knowledge. Decisional conflict will be measured by decisional conflict scale and knowledge will be evaluated by true/ false questions which provided by researchers. Actual mode of delivery (normal or cesarean) will be compared in two groups as a secondary outcome. 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. Data on mode of delivery will be obtained from hospital maternity records.

General information

Acronym

decision aids

IRCT registration information

IRCT registration number: **IRCT2013111010777N3**

Registration date: **2013-11-19, 1392/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-11-19, 1392/08/28

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

Investigator

Expected recruitment start date

2013-12-21, 1392/09/30

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of a computerized decision aids on the mode of delivery, compared with the conventional care

Public title

A computer based decision aids for mode of delivery (Natural delivery or Cesarean section)

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Positive pregnancy test, being in good health, Pregnancy above 28 weeks, and Singleton pregnancy; Exclusion criteria: unwanted pregnancy, inability to read and write and working with computer, experience of previous cesarean section

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Pregnant women were used as the unit of randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghoreishi building Daneshgah street

City

Mashhad

Postal code

۳۴۵ - ۹۱۳۷۵

Approval date

2013-02-02, 1391/11/14

Ethics committee reference number

511/4404

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 and after of the intervention

Method of measurement

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

2

Description

knowledge

Timepoint

Before and after of the intervention

Method of measurement

true/false questions

Secondary outcomes

1

Description

Mode of delivery

Timepoint

After the intervention

Method of measurement

Data available in the hospital records

Intervention groups

1

Description

Intervention group: they will receive a computer based decision aids on mode of delivery

Category

N/A

2

Description

Control group: they will receive the conventional care

Category

N/A

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
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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

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Science

Full name of responsible person
Azam Aslani M.

Position
PhD candidate of medical informatics

Other areas of specialty/work

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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