

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effect of group counseling versus not counseling on the knowledge, attitude and preference of delivery (prevention of cesarean) in fertile women: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of group counseling versus not counseling on the knowledge, attitude and preference of delivery (prevention of cesarean) in fertile women

Design

This is a randomized clinical trial, phase II, in which 90 eligible fertile women will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible fertile women who will refer to Health Centers of Hamadan City during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 18 to 35 years; willing pregnancy. Exclusion criteria: infertility; previous history of abortion or pregnancy; mental disease; chronic diseases such as diabetes, cardiovascular diseases, hypertension.

Intervention groups

Intervention group: routine care plus group counseling for 60 minutes weekly for 4 weeks. Control group: just routine care.

Main outcome variables

Preference of the type of delivery; the knowledge toward the type of delivery; the attitude toward the type of delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N239**
Registration date: **2018-09-29, 1397/07/07**
Registration timing: **prospective**

Last update: **2018-09-29, 1397/07/07**

Update count: **0**

Registration date

2018-09-29, 1397/07/07

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of group counseling versus not counseling on the knowledge, attitude and preference of delivery (prevention of cesarean) in fertile women: a randomized clinical trial

Public title

Effect of group counseling versus not counseling on the

knowledge, attitude and preference of delivery (prevention of cesarean) in fertile women

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18 to 35 years old Willing pregnancy
Exclusion criteria:
Infertility A previous history of abortion or pregnancy
Mental disease Chronic diseases such as diabetes, cardiovascular diseases, hypertension

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: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization

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 Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Approval date
2018-09-01, 1397/06/10
Ethics committee reference number
IR.UMSHA.REC.1397.404

Health conditions studied

1

Description of health condition studied

Caesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Assessing the preference of the type of delivery

Timepoint

Before intervention and one month after that

Method of measurement

Using a standard questionnaire

2

Description

Assessing the knowledge toward the type of delivery

Timepoint

Before intervention and one month after that

Method of measurement

Using a standard questionnaire

3

Description

Assessing the attitude toward the type of delivery

Timepoint

Before intervention and one month after that

Method of measurement

Using a standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine care plus group counseling for 60 minutes weekly for 4 weeks

Category

Prevention

2

Description

Control group: Just routine care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Centers of Hamadan City

Full name of responsible person

Maryam Ghafari Azandaryani

Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Email

m.ghafari@edu.umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Ghafari Azandaryani

Position

Midwifery Student

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Seyedeh Zahra Masoomi

Position

Fertility Health Specialist

Latest degree

Ph.D.

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available