

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Effect of educational program versus no cesarean rate in pregnant mothers: a clinical trial

Protocol summary

Summary

Objectives: To assess the effect of educational program versus no cesarean rate in pregnant mothers. Design: a clinical trial. Setting and conduct: The eligible pregnant mothers who will refer to Fatemieh or Atieh Hospitals during the study period will be enrolled into the trial. Inclusion criteria: Nulliparous pregnant women. Exclusion criteria: (a) history of abortion; (b) contraindication of physical activity. Intervention group 1: Routine pregnancy period education plus educational intervention program, 8 sessions, 60 hours each, from 20 weeks of gestational age, based on Ministry of Health protocol. Intervention group 2: Routine pregnancy period education plus educational intervention program, 8 sessions, 60 hours each, from 20 weeks of gestational age, based on researcher's need assessment. Control group: Only routine pregnancy period education. Primary outcome: Assessing the cesarean section rate at the end of pregnancy period based on medical records. Secondary outcome: Nothing. Randomization: Pregnant mothers who will refer to Fatemieh Hospital will receive the intervention and those who refer to Atieh Hospital will be considered as control. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512169014N86**
Registration date: **2015-12-26, 1394/10/05**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-26, 1394/10/05

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of educational program versus no cesarean rate in pregnant mothers: a clinical trial

Public title

Effect of educational program versus no cesarean rate in pregnant mothers

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Nulliparous pregnant women. Exclusion criteria: history of abortion; contraindication of physical activity.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Primary outcome: Assessing the cesarean section rate at the end of pregnancy period based on medical records.

Secondary outcome: Nothing.

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 the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2015-12-05, 1394/09/14

Ethics committee reference number

IR.UMSHA.REC.1394.399

Health conditions studied**1****Description of health condition studied**

Caesarean section

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes**1****Description**

Assessing the cesarean section rate

Timepoint

at the end of pregnancy period

Method of measurement

based on medical records

Secondary outcomes

empty

Intervention groups**1****Description**

Routine pregnancy period education plus educational intervention program, 8 sessions, 60 hours each, from 20 weeks of gestational age, based on Ministry of Health protocol

Category

Other

2**Description**

Routine pregnancy period education plus educational intervention program, 8 sessions, 60 hours each, from 20 weeks of gestational age, based on researcher's need assessment

Category

Other

3**Description**

Only routine pregnancy period education

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Fatemieh Hospital

Full name of responsible person

Marzieh Otoogara

Street address

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan
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**

Fatemieh Hospital

Full name of responsible person

Marzieh Otoogara

Position

PhD Student in Health Education

Other areas of specialty/work**Street address**

Fatemieh Hospital, Pasdaran Ave.

City

Hamadan

Postal code**Phone**

+98 81 3828 3939

Fax**Email**

m_otogara@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

School of Public Health

Full name of responsible person

Dr Akram Karimi Shahanjarini

Position

Assistant Professor of Health Education

Other areas of specialty/work**Street address**

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code**Phone**

+98 81 3838 0090

Fax**Email**

karimi.a@umsha.ac.ir

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Department of Epidemiology

Full name of responsible person

Dr Jalal Poorolajal

Position

Associate Professor

Other areas of specialty/work**Street address**

School of Public Health, Hamadan University of
Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Phone

+98 81 3838 0090

Fax**Email**

poorolajal@umsha.ac.ir

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