

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of education of physiological delivery in reducing the cesarean rate in pregnant women

Protocol summary

Summary

Objective: We aim to determine the effect of physiological birth in outcomes of delivery, including type of delivery, fear of delivery, pain of labor and apgar of neonate. Methods: A randomized controlled trial will complete on 160 women who admitting at Fatemieh hospital in Hamedan, Iran. 80 will allocate to physiological birth (intervention group) and 80 to routine vaginal birth (control group). The study population included all pregnant women with gestational age between 37 and 42 weeks; singleton pregnancy; live fetus; cephalic presentation; maternal age 18-45 years; and vaginal dilatation between 3 and 4 centimeter in examination room. In the intervention group education for physiological delivery are given in the 20th week of pregnancy for 8 weeks (one session per week). In this group, breathing techniques and relaxation training and exercise, nutrition during pregnancy and coping with stress is given. In the intervention group, during labor and delivery, the midwife will be along with mother and episiotomy incision is not given. But in the control group routine prenatal care will be performed and episiotomy may be given. The data collection instruments are included three questionnaires. Fear of delivery questionnaire, type of delivery check list, visual analogue scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072713405N4**

Registration date: **2014-11-14, 1393/08/23**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-11-14, 1393/08/23

Registrant information

Name

Seyyedeh Zahra Masoumi

Name of organization / entity

Hamedan University of Medical Sciences, School of Nursing and Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0150

Email address

zahra.masoomi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education of physiological delivery in reducing the cesarean rate in pregnant women

Public title

The effect of physiological birth on reduction of cesarean delivery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: No prohibition of normal vaginal

delivery; no known physical and mental illness; the absence of high risk pregnancy for example blood pressure 140.90 and higher, preeclampsia, polyhydramnios and oligohydramnios; absence of cesarean section history or any uterine scar and placenta previa; Lack of prolonged rupture of membranes more than 18 hours before delivery; estimation of fetal weight between 2500-4000 gr; absence of fetal congenital anomalies identified by ultrasound in perinatal Exclusion criteria: Blood pressure 140.90mmHg and higher during the intervention; failure to attend more than one session of training

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

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

Vice chancellor for research and technology, Hamedan University of Medical Sciences

Street address

Fahmideh Ave, Vice chancellor for research and technology, Hamedan University of Medical Sciences

City

Hamedan

Postal code

6516645977

Approval date

2012-02-01, 1390/11/12

Ethics committee reference number

16/35/9/3962/پ/د

Health conditions studied

1

Description of health condition studied

Relationship between education of physiological delivery and reducing cesarean birth

ICD-10 code

O80.0

ICD-10 code description

Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Type of delivery

Timepoint

Immediately after delivery

Method of measurement

Questionnaire

2

Description

Fear of delivery

Timepoint

Before education and after delivery

Method of measurement

Questionnaire

3

Description

Pain of delivery

Timepoint

After delivery

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Apgar

Timepoint

After delivery

Method of measurement

Check list

Intervention groups

1

Description

Intervention group: physiological birth

Category

Prevention

2

Description

Control group: Routine normal delivery
Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Street address
City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for Research the Technology,
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeed Bashiriyani
Street address
Hamedan University of Medical Sciences, Fahmideh
Ave, Hamedan,Iran
City
Hamedan
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, Hamedan
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
Hamedan University of Medical Sciences
Full name of responsible person
Seyedeh Zahra Masoumi
Position
PhD in reproductive health
Other areas of specialty/work
Street address

Fahmideh Ave, School of nursing and midwifery,
Hamedan University of Medical Sciences, Hamedan,
Iran

City

Hamedan

Postal code

6516845977

Phone

+98 81 3838 0150

Fax

+98 81 3838 0447

Email

zahramid2001@yahoo.com;
zahra.masoomi@umsha.ac.it

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Seyedeh Zahra Masoumi
Position
PhD of reproductive health
Other areas of specialty/work
Street address
Fahmideh Ave, School of Nursing and Midwifery,
Hamedan University of Medical Sciences, Hamedan,
Iran
City
Hamedan
Postal code
6516645977
Phone
+98 81 3838 0150
Fax
+98 81 3838 0447
Email
zahramid2001@yahoo.com;
zahra.masoomi@umsha.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Seyedeh Zahra Masoumi
Position
Instructor, PhD of reproductive health
Other areas of specialty/work
Street address
Fahmideh Ave, Hamedan university of medical
sciences, school of nursing and midwifery, Hamedan,
Iran
City
Hamedan
Postal code
6516845977

Phone

+98 81 3838 0150

Fax

+98 81 3838 0447

Email

zahramid2001@yahoo.com;

zahra.masoomi@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