Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 20 th 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
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Iran (Islamic Republic of)
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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, polyhydramniosis and oligohydramniosis; 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/د/پ

Health conditions studied

1

Description of health condition studied
Relationship between education of physiological delivery and reducing cesaren 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
Intevention 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 Bashiriyan

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

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Position

Instructor, PhD of reproductive health

Other areas of specialty/work

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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