

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Designing of educational, financial and revisional interventions of human factors and structural agents on cesarean rate reduction , administration and evaluation of them in Shahroud and comparison with cesarean rate in adjacent cities

Protocol summary

Summary

The present study is an integrative multilateral program that aims to maternal and neonatal health promotion.

Objectives: 1- To determine perceived threat of unnecessary cesarean morbidity in pregnant women 2- To determine perceived self efficacy of unnecessary cesarean morbidity in pregnant women 3-To determine women 'intention to delivery mode in pregnant women 4-To determine women 'knowledge about delivery mode in pregnant women 5- To increase women's intention at least 80% to vaginal birth at the end of the educational sessions 6-To increase cesarean rate of participants in Shahroud in comparison of participants in other cities of Semnan Province Our approach concludes two stages:1- Designing the model 2- Administrating and evaluation of model Designing the model comprise the main factors effect on decision and performing cesarean surgery. Our interventions conclude: 1- Goal oriented trainings of birth skills to obstetricians and midwives in Shahroud to instruct the pregnant mothers 2- Structured instructions to pregnant women in prenatal classes during 8 sessions 3- Revision of fee for services for obstetricians, anesthesiologists and midwives 4- Amending the labor/delivery ward in order to decrease the fear and anxiety of labored women Sample size is 220 pregnant women in experiment and control groups Interventions: Instructions of necessary educations about physiologic delivery on the basis of "Extended Parallel Process Model" or EPPM during 8 sessions as prenatal educations and learning pain and fear control skills for childbirth for women in experiment group, whereas women in control do not get such educations but regular prenatal care. Inventory is a structured questionnaire through EPPM that will be given participants in experiment group before and after educations and subjects in control group near the expected date of delivery. Main constructs of

EPPM and "knowledge and intention" will be compared in two groups. Final outcome is the mode of delivery that will be compared in two groups and the effectiveness of educations will be evaluated. Inclusion criteria include: no history of former cesarean of uterine surgery , general wellbeing with no indication for medical/surgical intervention , Persian literacy , singleton pregnancy and cephalic presentation , No scientific approved indication for cesarean surgery , Being at 18 gestational weeks and singleton pregnancy and cephalic presentation Exclusion criteria: Every induced systemic disease during present pregnancy which needs to medical or surgical intervention and every obstetrical/non obstetrical indication for cesarean section Finally, cesarean rates will be compared in Shahroud and other adjacent cities in Semnan Province during study time

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106215525N2**

Registration date: **2011-06-27, 1390/04/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-27, 1390/04/06

Registrant information

Name

Sepidh Hajian

Name of organization / entity

Sharoud Mdical Science University

Country

Iran (Islamic Republic of)

Phone	+98 27 3339 5054	Placebo	Not used
Email address	hajia@shmu.ac.ir	Assignment	Parallel
Recruitment status		Other design features	
Recruitment complete		Secondary Ids	
Funding source	Vice chancellor for research and education , Shahroud University of Medical Sciences with collaboration of Health Deputy, Treatment Deputy and Logistic Deputy.	Ethics committees	
Expected recruitment start date	2010-12-22, 1389/10/01	1	
Expected recruitment end date	2011-10-23, 1390/08/01	Ethics committee	
Actual recruitment start date	empty	Name of ethics committee	Ethics Committee of Shahroud University of Medical Sciences
Actual recruitment end date	empty	Street address	Shahroud University of Medical Sciences, 7th Tir Sq, Sharoud, Iran
Trial completion date	empty	City	Shahroud
Scientific title	Designing of educational,financial and revisional interventions of human factors and structural agents on cesarean rate reduction ,administration and evaluation of them in Shahroud and comparison with cesarean rate in adjacent cities	Postal code	
Public title	Cesarean rate reduction model	Approval date	2011-02-16, 1389/11/27
Purpose	Prevention	Ethics committee reference number	890/07
Inclusion/Exclusion criteria	Inclusion criteria include: No history of former cesarean of uterine surgery, general wellbeing with no indication for medical/surgical intervention , Persian literacy 4-singleton pregnancy and cephalic presentation , No scientific approved indication for cesarean surgery , Being at 18 gestational weeks , singleton pregnancy and cephalic presentation Exclusion criteria conclude: Every induced systemic disease during present pregnancy which needs to medical or surgical intervention, and every obstetrical/non obstetrical indication for cesarean section	Health conditions studied	
Age	From 18 years old to 40 years old	1	
Gender	Female	Description of health condition studied	Factors influencing health status and contact with health services
Phase	2-3	ICD-10 code	Z34
Groups that have been masked	No information	ICD-10 code description	Supervision of normal pregnancy
Sample size	Target sample size: 220	Primary outcomes	
Randomization (investigator's opinion)	N/A	1	
Randomization description		Description	cesarean delivery
Blinding (investigator's opinion)	Not blinded	Timepoint	at the end of study
Blinding description		Method of measurement	calculating
		Secondary outcomes	
		1	
		Description	self efficacy
		Timepoint	before and after prenatal educations
		Method of measurement	

questionnaire

2

Description

knowledge

Timepoint

before and after prenatal educations

Method of measurement

questionnaire

3

Description

intention

Timepoint

before and after prenatal educations

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention in experiment group: 1- Prenatal educations mainly based on "Extended Parallel Process Model" are an essential intervention that will be given to 220 participants through 8 sessions. This Model discuss about fear incentive of health threatening factor that in the present study includes fear from potential threats of unnecessary cesarean section. These educations will be presented by trained midwives in maternal health centers in Shahroud .Women in control group will be given prenatal routine care. 2- Instructions to obstetricians and midwives on the basis of confirmed context provided by The Ministry of Health and Medical Education 3- Revision of labor/delivery wards space in Shahroud hospitals in order to applying coping skills (relaxation, breathing and maternal position amending) to reduce pain and anxiety during labor/delivery. 4- Increasing the fee for services of obstetricians, anesthesiologists and midwives in cases of vaginal delivery to avoiding unnecessary cesarean which may perform due to financial motivations.

Category

Prevention

2

Description

Participants in control group will not be educated likewise the intervention group on the basis of foregoing Model and will be given routine care

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Head of Delivery Ward , Dr.Said-e- Roghayeh Mirmajidi

Street address

Delivery Ward, Imam Hossein Hospital, Shahroud

City

Shahroud

2

Recruitment center

Name of recruitment center

Fatemiye Hospital

Full name of responsible person

Chairman of Obstetrics & Gynecology Department, Dr.Mohammad Esmaeel Ajami

Street address

Delivery Ward, Fatemiye Hospital, 22Bahman Avenue, Shahroud

City

Shahroud

3

Recruitment center

Name of recruitment center

Azima health center

Full name of responsible person

Ms Fatemeh Khoda Bakhshi

Street address

Midwifery unit, Azima health center, Ferdosi Avenue, Shahroud

City

Shahroud

4

Recruitment center

Name of recruitment center

Shahid Sadri health center

Full name of responsible person

Ms Fahimeh Zolfaghari

Street address

Midwifery Unit, Shahid Sadri health center, Bagh Zendan Crossroad, Shahroud

City

Shahroud

5

Recruitment center

Name of recruitment center

Shahid Boujar health center

Full name of responsible person

Ms Zahra Ajoudani

Street address

Midwifery Unit, Shahid Boujar health center, Ayatollah Madani Blvd., Sahrud

City

Shahroud

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Recruitment center

Name of recruitment center

Shohada-e- Mehdi abad health center

Full name of responsible person

Ms Fatemrh Zahra Ghasemi

Street address

Midwifery Unit, Shohada-e- Mehdi abad health center,
12St., Mehdi abad district, Shahroud

City

Shahroud

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Recruitment center

Name of recruitment center

Bahar local health center

Full name of responsible person

Ms Karimi

Street address

Midwifery unit, Bahar local health center, Baharestan
District, Shahroud

City

Shahroud

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Recruitment center

Name of recruitment center

Shahrak Emam health center

Full name of responsible person

Ms Esmat Tahanian

Street address

Midwifery unit, Shahrak Emam health center, Shahrak
-e- Emam, Ayatollah Kashani Blvd., Shahroud

City

Shahroud

9

Recruitment center

Name of recruitment center

Shahid Mohammadi Health Center

Full name of responsible person

Ms Nooshin Ahmadian

Street address

Midwifery unit, Shahid Mohammadi Health Center,
Pishva St., Emam Avenue, Shahroud

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahroud University of
Medical Sciences

Full name of responsible person

Dr.Sayed Abbas Mousavi

Street address

Vice chancellor for research, Shahroud University of
Medical Sciences, 7th Tir Sq., Shahroud

City

Sahroud

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, Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Sepideh Hajian

Position

PhD student

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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