Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Design, implementation and evaluation of intervention program for normal vaginal Birth after cesarean section

Protocol summary

Study aim
Determining and comparing mothers' satisfaction and childbirth outcomes in the intervention and control groups after the intervention

Design
Clinical trial with control group, with parallel groups, randomized, on 50 pregnant mothers, randomization will be done with the help of Excel software.

Settings and conduct
Eligible pregnant women will be placed in one of two test and control groups using computer randomization with Excel software. In addition to routine pregnancy care, the test group will participate in birth preparation classes and acupressure sessions and prepare for a natural delivery. The control group will only undergo routine pregnancy care and will eventually undergo repeated cesarean section.

Participants/Inclusion and exclusion criteria
Women with a history of cesarean section in the age group under 40 years old with a history of transverse cesarean section

Intervention groups
Natural childbirth in the intervention group and repeat cesarean section in the control group

Main outcome variables
Birth outcomes; mothers' satisfaction; the number of natural births after caesarean section, the relative frequency of mothers referring for natural births after caesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091219002889N14**
Registration date: **2023-04-02, 1402/01/13**
Registration timing: **prospective**
Last update: **2023-04-02, 1402/01/13**
Update count: **0**

Registration date
2023-04-02, 1402/01/13

Registrant information

Name
Mahboubeh Valiani

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3651 4640

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-21, 1402/02/01

Expected recruitment end date
2025-03-20, 1403/12/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Design, implementation and evaluation of intervention program for normal vaginal Birth after cesarean section

Public title
Vaginal Birth after cesarean section in women with a history of cesarean section

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian nationality Resident of Isfahan city Score 5 and above according to Flam et al 's scoring table No history of known mental disorders based on the contents of the file Age less than 40 years Normal vital signs of the mother No history of intrauterine death (IUFD) Absence of the cause of previous cesarean including: long labor, presentation of breech, fetal distress Single embryo Lack of track record Absence of pelvic stenosis History of transverse cesarean section Normal body mass index (19.8-24) Current non-pregnancy with assisted reproduction methods The interval between the current pregnancy and the previous cesarean delivery is at least 18 months Absence of any disease or complication that hinders natural delivery according to gynecologist Willingness to participate in the study

Exclusion criteria:
Twin pregnancy Previous cesarean vertical incision Unwillingness to participate in the study Body mass index above 25 Non-Iranian nationality Pregnancy with the help of assisted reproduction methods Suffering from a disease or complication that, according to experts, prohibits natural childbirth

Age
To **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
By referring to the research environment, the researcher will take a detailed medical and obstetric history from the mothers who have a history of one cesarean section, and after reviewing the entry criteria and explaining the objectives and methods of the study, he will suggest participation in the research to the participants. and will obtain written informed consent from them to participate in the study. The randomization method will be simple and individual. Eligible pregnant women will be placed in one of two test and control groups using computer randomization with Excel software.

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
Ethical Committee of Isfahan University of Medical Sciences

Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services, central headquarters

City
Esfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2023-03-11, 1401/12/20

Ethics committee reference number
IR.MUI.NUREMA.REC.1401.175

Health conditions studied

1

Description of health condition studied
Vaginal Birth after Cesarian

ICD-10 code
O75.7

ICD-10 code description
Vaginal delivery following previous caesarean section

Primary outcomes

1

Description
Mother's satisfaction

Timepoint
In 24 hours after delivery

Method of measurement
Questionnaire of satisfaction of natural childbirth and cesarean delivery by Pakari et al

2

Description
Obstetric outcomes

Timepoint
The first 24 hours after delivery

Method of measurement
Checklist made by the researcher

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Women with a history of previous caesarean section in their current pregnancy will undergo natural delivery intervention
Category
N/A

2

Description
Control group: Women with a history of caesarean section in the current pregnancy will undergo a repeat cesarean section
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
All hospitals under the supervision of Isfahan University of Medical Sciences
Full name of responsible person
mahboobeh valiani
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. GholamReza Asgari
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Building No. 4 - Vice-Chancellor for Research and Technology of the University
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research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mahboobeh Valiani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Care Services, Nursing and Midwifery College
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The main implications of the study will be shared

When the data will become available and for how long
Data access starts 6 months after results are published

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
For the knowledge and use of other researchers in their next similar studies

From where data/document is obtainable
Email: valiani@nm.mui.ac.ir

What processes are involved for a request to access data/document
The researcher must send a request to send information with a valid organizational email or university email

Comments