

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)

Phone

+98 31 3651 4640

Email address

valiani@nm.mui.ac.ir

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

Isfahan

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

City

Esfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 913 319 7959

Email

valiani@nm.mui.ac.ir

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

City

Esfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3668 5149

Email

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

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7537

Email

valiani@nm.mui.ac.ir

Person responsible for scientific 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

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7537

Email

Valiani@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahbooneh 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

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 7537

Email

Valiani@nm.mui.ac.ir

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