

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing Cesarean Scar Defect Incidence After Locked and Unlocked Repair Methods Among Primiparous Patients: A Randomized Double-blinded Trial

Protocol summary

Study aim

To evaluate and compare the effects of double-layer locked and unlocked uterine closure techniques in the incidence of cesarean scar defect following the cesarean section

Design

Two-arm parallel-group randomised trial with blinded postoperative care and outcome assessment, with a random block allocation method

Settings and conduct

Patients who meet the inclusion criteria and are candidates for cesarean section in Imam Khomeini Hospital of Tehran are included in this study and are randomly allocated to Locked or Unlocked. The patient will not be aware of the repair method. Then, one year after the operation, the patients are subjected to sonographic examination by an experienced obstetrician and gynecologist of the center who is not aware of their repair method.

Participants/Inclusion and exclusion criteria

Inclusion criteria - primiparous term pregnant women in their third trimester - eligible for primary cesarean section - possessing a normal pre-pregnancy body mass index - lacking pre-pregnancy medical conditions - free from major pregnancy complications like gestational hypertension, preeclampsia, eclampsia, and gestational diabetes mellitus - not in the latent phase of labor - presenting with a fetal head station of zero or higher - no history of prior lower uterine segment surgery. Exclusion criteria - extension of the cesarean section incision during the procedure - Pregnancy during the one-year follow-up period - patient unwillingness - patient non-cooperation

Intervention groups

Patients will randomly be assigned to one of two groups: "locked" or "unlocked" uterine closure methods. In the locked group, a two-layer closure was performed, while

in the unlocked group, a two-layer closure will be also carried out.

Main outcome variables

- Scar depth - Scar width - Presence/absence of cesarean scar defect - Residual myometrial thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231028059887N1**

Registration date: **2024-01-17, 1402/10/27**

Registration timing: **retrospective**

Last update: **2024-01-17, 1402/10/27**

Update count: **0**

Registration date

2024-01-17, 1402/10/27

Registrant information

Name

Mohammadamin Parsaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7784 1829

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amin.parsaei890@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2022-03-10, 1400/12/19

Actual recruitment start date

2021-04-01, 1400/01/12

Actual recruitment end date

2022-04-01, 1401/01/12

Trial completion date

2023-04-01, 1402/01/12

Scientific title

Comparing Cesarean Scar Defect Incidence After Locked and Unlocked Repair Methods Among Primiparous Patients: A Randomized Double-blinded Trial

Public title

Comparing Cesarean Scar Defect Incidence After Locked and Unlocked Repair Methods Among Primiparous Patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Primiparous term pregnant women in their third trimester Eligible for primary cesarean section Possessing a normal pre-pregnancy body mass index (BMI) Lacking pre-pregnancy medical conditions Free from major pregnancy complications like gestational hypertension, preeclampsia, eclampsia, and gestational diabetes mellitus Not in the latent phase of labor Presenting with a fetal head station of zero or higher (-3, -2, -1, and 0) No history of prior lower uterine segment surgery

Exclusion criteria:

Extension of the cesarean section incision during the procedure Pregnancy during the one-year follow-up period Patient unwillingness Patient non-cooperation

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to the "locked" and "unlocked" uterine closure methods using a random block allocation method (allocation ratio of 1:1, blocks of four).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the examiner who performed the ultrasonographic assessments were blinded to the surgical closure approach assignments.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address

Keshavarz blvd, Gharib st, Imam Khomeini Hospital Complex, Tehrna, Iran

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Tehran

Province

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Postal code

1419733141

Approval date

2021-03-03, 1399/12/13

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.523

Health conditions studied**1****Description of health condition studied**

Cesarean scar defect

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Residual myometrial thickness

Timepoint

one year following the cesarean section

Method of measurement

ultrasonographic examination by an experienced obstetrics and gynecologist specialist

2**Description**

scar depth

Timepoint

one year following the cesarean section

Method of measurement

ultrasonographic examination by an experienced obstetrics and gynecologist specialist

3

Description

scar width

Timepoint

one year following the cesarean section

Method of measurement

ultrasonographic examination by an experienced obstetrics and gynecologist specialist

4

Description

presence/absence of cesarean scar defect (defined as scar depth larger than 2 millimeters)

Timepoint

one year following the cesarean section

Method of measurement

ultrasonographic examination by an experienced obstetrics and gynecologist specialist

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: Two-layer locked uterine closure following the cesarean section

Category

Treatment - Surgery

2

Description

Second intervention group: Two-layer unlocked uterine closure following the cesarean section

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Azadeh Tarafdari Manshadi

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Keshavarz blvd, Gharib st, Imam Khomeini Hospital Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Keshavarz Blvd., Quds St., Central Organization of the Tehran University of Medical Sciences, 6th floor, Research and Technology section

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Azadeh Tarafdari Manshadi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Mohammadamin Parsaei

Position

Postdoctoral Research Fellow

Latest degree

Medical doctor

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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

Baseline demographic data of the participants and results of their follow-up visits (ultrasonographic examination) would be available in an SPSS file (with a sav. format)

When the data will become available and for how long

Data would be available six months after the publication

To whom data/document is available

Researchers of the university-based research centers

Under which criteria data/document could be used

In cases of proper requests and under our supervision the data would be available.

From where data/document is obtainable

Email address: Amin.parsaei890@gmail.com

What processes are involved for a request to access data/document

Emailing the author and explaining the reason for their request Confirming the adherence to ethical considerations Receiving the data via email

Comments