Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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
City
Tehran
Province
Tehran
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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Akbar Fotouhi
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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
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Azadeh Tarafdari Manshadi
Position
Associate Professor
Latest degree
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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