

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the incidence of cesarean scar niche in 4 methods of myometrial repair in single and double layer with chromic and vicryl sutures

Protocol summary

Study aim

Comparison of frequency distribution of niche after cesarean section in 4 methods of single layer and double layer myometrial repair with vicryl and chromic sutures

Design

The clinical trial consisted of 4 intervention groups, double-blind, randomized on a total of 108 patients (each group included 27 patients). Patients were enrolled by convenience sampling method and randomized blocking was performed.

Settings and conduct

In this study, 108 pregnant women referring to the clinic and delivery room of Taleghani Hospital in Tehran who are experiencing their first cesarean section will be included in the study based on inclusion and exclusion criteria. Patients will be placed in one of 4 repair groups (without knowing the repair method). After at least 6 months of cesarean section, they will refer to an ultrasound specialist who specializes in examining cesarean scar niche, who will inform the closure method and will report the size of the niche and the residual myometrium thickness(RMT).

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with a singleton pregnancy over 37 weeks of gestation who will undergo elective or emergency cesarean section for the first time. Exclusion criteria: chorioamnionitis; history of previous uterine myometrial surgery; classic uterine incision; placenta accreta or previa.

Intervention groups

Patients will be randomly divided into 4 groups: Group 1: Single layer closure of kerr incision with continuous_lock vicryl suture. Group 2: Double layer closure of kerr incision(first layer: continuous lock and second layer: continuous) with vicryl suture. Group 3: Single layer closure of kerr incision with continuous_lock chromic suture. Group 4: Double layer closure of kerr incision(first

layer: continuous lock and second layer: continuous) with chromic suture.

Main outcome variables

Niche; RMT; single/double-layer myometrial repair

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220531055036N1**

Registration date: **2022-11-14, 1401/08/23**

Registration timing: **retrospective**

Last update: **2022-11-14, 1401/08/23**

Update count: **0**

Registration date

2022-11-14, 1401/08/23

Registrant information

Name

Mahsa Mirhadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2560

Email address

m.a.mirhadi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the incidence of cesarean scar niche in 4 methods of myometrial repair in single and double layer with chromic and vicryl sutures

Public title
The effect of myometrial repair technique on the incidence of niche.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
First cesarean section Gestational age more than 37 weeks Kerr incision Singleton pregnancy
Exclusion criteria:
Chorioamnionitis Previous myometrial surgery Classic incision Placenta accreta or previa

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **108**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomized (There are 4 blocks and the number of people in each block is 27 and patients are placed in one block, respectively.)

Blinding (investigator's opinion)
Double blinded

Blinding description
Sonographer and patient are not aware of myometrial repair methods.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid beheshti university of medical sciences

Street address

Taleghani hospital, Erabi Ave, daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

1985717413

Approval date

2022-05-28, 1401/03/07

Ethics committee reference number

IR.SBMU.MSP.REC.1401.102

Health conditions studied

1

Description of health condition studied

Cesarean scar

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Niche

Timepoint

6 months after cesarean section

Method of measurement

Ultrasound

Secondary outcomes

1

Description

Residual myometrium thickness

Timepoint

6 months after cesarean section

Method of measurement

Ultrasound

Intervention groups

1

Description

The myometrium is repaired in one layer with vicryl no. 1 suture (polyglactin 910).

Category

Treatment - Surgery

2

Description

The myometrium is repaired in two layer with vicryl no. 1 suture(polyglactin 910).

Category

Treatment - Surgery

3

Description

The myometrium is repaired in one layer with chromic no. 1 suture(natural absorbable suture).

Category

Treatment - Surgery

4

Description

The myometrium is repaired in two layer with chromic no. 1 suture(natural absorbable suture).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Mahsasadat Mirhadi

Street address

Erabi Ave., Taleghani hospital

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Email

taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Sahid Beheshi Univerdity of Medical Science, Erabi Ave., Yaman Ave.

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Tehran

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Postal code

1985717443

Phone

+98 21 23871

Email

info@sbmu.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahsasadat Mirhadi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Position

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Latest degree

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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

All data except personal information (including patients' names, addresses and telephone numbers) can be shared.

When the data will become available and for how long

Start accessing after printing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Using data for research and treatment.

From where data/document is obtainable

M.a.mirhadi@sbmu.ac.ir Mahsasadat Mirhadi

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

After confirming the identity of the applicant from the university, information will be made available to him / her in case of non-contradiction with ethical issues and approval of the supervisor.

Comments