

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of a new method used for uterine closure during cesarean section on the integrity and thickness of uterine scar.

Protocol summary

Study aim

The aim of this randomized controlled trial is to compare the effects of new and conventional technique for uterine closure during cesarean delivery on primary and secondary outcomes.

Design

This study is a parallel-group double-blind, randomized controlled trial. 70 pregnant women will be randomly divided into two groups of 35 each using a table of random numbers.

Settings and conduct

This is a double blind randomized controlled trial. study Population consist of pregnant women who are undergoing cesarean section for the first time. The setting of study are two hospitals (Hazrat-e Rasool Akram and firooz Abadi) affiliated to Iran University of Medical of Science. Study objectives will be explained to pregnant women who are candidate for cesarean section and informed written consent will be taken. 70 Pregnant women will be randomly divided into two groups (intervention and control) by using computer-generated table of random numbers. In the intervention group, cesarean section incision will be closed with new technique. In the control, group cesarean section incision will be closed by conventional technique. Double blinding (blinding participants, and investigators consist of interpreter statistician and sonologist) will be used to reduce the selection bias.

Participants/Inclusion and exclusion criteria

Population of study are pregnant women who are undergoing cesarean section for the first time.

Intervention groups

There will be two intervention and control groups in this study. In the intervention group, cesarean section incision will be closed with the new technique. In control group, cesarean section incision will be closed by the conventional technique.

Main outcome variables

The primary outcomes are uterine closure time and

primary postpartum hemorrhage. The secondary outcome is to compare the residual myometrial thickness and the depth of cesarean section scar defect after uterine incision closure using the new technique with the conventional technique.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160527028109N2**

Registration date: **2018-03-06, 1396/12/15**

Registration timing: **prospective**

Last update: **2018-03-06, 1396/12/15**

Update count: **0**

Registration date

2018-03-06, 1396/12/15

Registrant information

Name

Kobra Tahermanesh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of a new method used for uterine closure during cesarean section on the integrity and thickness of uterine scar.

Public title

Evaluation of a new method used for uterine closure during cesarean section on the integrity and thickness of uterine scar.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women submitted to cesarean section for the first time

Exclusion criteria:

Presence of uterine anomalies with or without previous repair. Presence of uterine myoma at the site of caesarean incision History of myomectomy at site of caesarean incision Presence of placenta previa and placenta accrete. Prolonged rupture of membranes without chorioamnionitis criteria (consist of fever, uterine tenderness...) Rupture of membranes with chorioamnionitis criteria (consist of fever, uterine tenderness...)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study 70 pregnant women will be divided into two groups of 35 each using a computer-generated table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blinding (blinding participants, and investigators consisting of statistician and specialist in sonography) will be used to reduce the selection bias.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

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Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-12-14, 1396/09/23

Ethics committee reference number

IR.IUMS.REC 1396.32133

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

New method for uterine closure during cesarean delivery

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

The primary outcomes are uterine closure time and primary postpartum hemorrhage.

Timepoint

During and the day after surgery

Method of measurement

Chronometer, Complete Blood Count(CBC), Medical records of patients

Secondary outcomes**1****Description**

The secondary outcome is to compare the residual myometrial thickness and the depth of cesarean section scar defect after uterine incision closure using the new technique with the conventional method.

Timepoint

3 months after the surgery

Method of measurement

Ultrasound examination will be performed 3 months after the operation to assess the integrity of scar by

measuring the residual myometrial thickness and the depth of the possible scar defect.

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Intervention groups

1

Description

Intervention group: In intervention group cesarean section incision will be closed with new technique. The surgical technique in this group is described as follows: Step 1. After securing the angle of the incision, a full thickness needle bite is taken starting 1 cm away from the margin of the incision and coming out in an oblique fashion at the junction of the myometrium and decidua of the lower edge of the incision. We then enter at the junction of the myometrium and decidua of the upper edge of the incision, and come out 1 cm away from the margin of the upper edge. Step 2. Without changing the direction of the needle, a superficial bite about 0.5 cm away from the edge of incision with depth of 0.5 cm is encircling the outer margins. Step 3. At this stage, two loose loops are formed at the cranial and caudal end. The assistant will pull the first and then the second loops until the loops get tightened by pulling the thread. The surgeon continues the same process for the next bite. This technique will ensure full thickness decidua-to-decidua, myometrium-to-myometrium and serosa-to-serosa approximation of the uterine cut margins with good homeostasis. Antibiotic administration is according to the standard protocol.

Category

Treatment - Surgery

2

Description

In control group cesarean section incision will be closed by the conventional technique.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Kobra Tahermanesh

Street address

Rasoul Akram Hospital, Satarkhan St, Tehran

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Recruitment center

Name of recruitment center

Firooz Abadi hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Vice Chancellor for Administration of Iran University of Medical Sciences (IUMS)

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Kobra Tahermanesh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

There is no more information

When the data will become available and for how long

After article publishing

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

There is no more information

From where data/document is obtainable

Endometriosis Research Center 0098 21 66509283

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

There is no more information

Comments