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 Populationconsist 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)

Phone

+98 21 6435 2562

Email address

tahermanesh.k@iums.ac.ir

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
City
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 surgry
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.

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

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 6650 9283

Email
tahermanesh.k@iums.ac.ir

2

Recruitment center

Name of recruitment center
Firooz Abadi hospital

Full name of responsible person
Kobra Tahermanesh

Street address
Firooz Abadi Hospital, Fadayan-e-Eslam,Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 5590 2064

Email
tahermanesh.k@iums.ac.ir

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)

Street address
Iran University of Medical Science, Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1449614535

Phone
+98 21 86701

Email
tahermanesh.k@iums.ac.ir

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
Street address
Rasoul Akram Hospital, Satarkhan St, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 64351
Email
tahermanesh.k@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kobra Tahermanesh
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Rasoul Akram Hospital, Satarkhan St, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 64351
Email
tahermanesh.k@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kobra Tahermanesh
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Rasoul Akram Hospital, Satarkhan St,Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 64351
Email
tahermanesh.k@iums.ac.ir

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
Tahermanesh.k@iums.ac.ir
What processes are involved for a request to access data/document
There is no more information
Comments