Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

A Comparison of the Effect of two Suture Materials on Isthmocele Formation after Cesarean section

Protocol summary

Study aim

A Comparison of the Effect of two suture materials on Isthmocele formation after cesarean

Design

150 pregnant women who meet the inclusion criteria by random block method will be divided into two groups using chrome and vicryl yarn. Using the balanced block randomization method, we form 6 blocks of 4 from B and A. Then, based on the table of random numbers, we assign 1 to 6 to the blocks, and in the second step, we put the blocks together based on the coincidence. In this way, there will be an equal number of two groups in each block and we will continue the sampling process until we reach the desired sample size. Data analysis will be done using SPSS statistical software version 24

Settings and conduct

150 pregnant women with eligibility criteria who undergo cesarean delivery in Kowsar Medical Center (affiliated to Qazvin University of Medical Sciences) since 2022 after obtaining written consent to cooperate are randomly selected. To reduce bias, single-blind method is used in such a way that the sonographer does not know the type of thread used in cesarean section.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age over 18 years 2- Single pregnancy 3- Gestational age over 38 weeks 4- First cesarean section Exclusion indications: 1- Multifetal pregnancy 2- History of previous cesarean section 3- History of uterine surgery such as myomectomy 4- Cesarean section in active labor phase (dilation above 4 cm) 5- Diabetes 6- Chronic hypertension 7- Preeclampsia 8- Anemia (Hb <10/5)

Intervention groups

Patients will be randomly divided into two groups using chrome and vicryl yarn.

Main outcome variables

Isthmocell formation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220507054766N1**
Registration date: **2022-08-08, 1401/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-08, 1401/05/17**
Update count: **0**

Registration date

2022-08-08, 1401/05/17

Registrant information

Name

samane nasiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3378 6861

Email address

snasiri550@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-08, 1401/02/18

Expected recruitment end date

2023-03-09, 1401/12/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of the Effect of two Suture Materials on Isthmocele Formation after Cesarean section

Public title
A Comparison of the Effect of two Suture Materials on Isthmocele Formation after Cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years Single tone pregnancy Gestational age over 38 weeks First cesarean section

Exclusion criteria:
History of uterine surgery such as myomectomy Cesarean section in the active phase of labor (dilation above 4 cm) Diabetes Chronic blood pressure Preeclampsia Anemia (Hb <10/5)

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples will be divided into two groups by balanced blocked randomization. Blocking and sequencing of samples will be done with random allocation software (Random Allocation Software 1.0) and will include 25 blocks of 6. In order to conceal the random allocation process, the names of the groups were placed in envelopes, numbered from 1 to 150 on these envelopes and arranged in a box, the contents of the envelopes indicated the study groups. And after ensuring that the sample enters the research and obtaining written consent, the first envelope is taken in order of number and according to the content of the envelope, they are placed in one of the study groups

Blinding (investigator's opinion)
Single blinded

Blinding description
The sonologist does not know the type of suture used to close the uterine incision.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
No 33, 7 Erfan, komil ave

City
qazvin

Province
Qazvin

Postal code
3471956654

Approval date
2022-04-30, 1401/02/10

Ethics committee reference number
IR.QUMS.REC.1401.018

Health conditions studied

1

Description of health condition studied
A comparison of the effect of two suture materials on isthmocele formation after cesarean

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Isthmocell formation

Timepoint
Examination of isthmocell formation 3 months after cesarean section

Method of measurement
Using ultrasound

Secondary outcomes

1

Description
Duration of operation,

Timepoint
Time recorded in the file

Method of measurement
Based on the information in the patient file

2

Description
amount of bleeding during surgery

Timepoint
6 hours after surgery

Method of measurement
Primary hemoglobin minus hemoglobin 6 hours after surgery

3

Description
Spotting
Timepoint
3 months after surgery
Method of measurement
Question from the patient

Intervention groups

1

Description
Use of chrome thread to repair hysterotomy in cesarean section/ Chromic CAT GUT surgical sutures of Kayhan Teb Company are taken from cleaned connective tissue (collagen) and are prepared from sheep intestines. These yarns are packed in a solution of 90% alcohol, 2% glycerin and 8% distilled water. Chromic CAT GUT suture is impregnated with a solution of chromic salts.
Category
Treatment - Devices

2

Description
Use of vicryl suture to repair hysterotomy in cesarean section /PGA is a sterile absorbable synthetic suture (vicryl) suture from Tamin Salamat Company, which is composed of polyglycolic acid polymer. The multi-strand woven yarn is coated with a mixture of calcium stearate and polycaprolactone to reduce yarn friction with the fabric. PGA suture is available in purple and colorless form (white). PGA suture meets the requirements of European and American pharmacopoeia.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
Samane Nasiri
Street address
Valiasr Street
City
Qazvin
Province
Qazvin
Postal code
3415613176
Phone
+98 28 3324 2661
Email
itkosar@qums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Samane nasiri
Street address
Valiasr Street
City
Qazvin
Province
Qazvin
Postal code
3415613176
Phone
+98 28 3324 2661
Email
itkosar@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Samane nasiri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Email

snasiri550@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Farideh Movahed

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Valiasr Street

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Postal code

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Phone

+98 28 3324 2661

Email

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Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Samane nasiri

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

No. 33, Kamil Erfan St.

City

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Province

Qazvin

Postal code

3471956654

Phone

+98 28 3378 6861

Email

snasiri550@gmail.com

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 of this research will be available

When the data will become available and for how long

Six months after the results were published

To whom data/document is available

It will be accessible to everyone

Under which criteria data/document could be used

-

From where data/document is obtainable

website

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

-

Comments