

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of chromium and vicryl yarn on the extent and severity of cesarean scar defects (nich) in patients undergoing cesarean section

Protocol summary

Study aim

Determining the relationship between the type of suture used and the incidence and severity of cesarean scar defects (nich) in patients with a history of cesarean

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, was performed on 50 women who underwent cesarean section, and randomization was performed based on a table of random numbers in two groups of 25 people.

Settings and conduct

The effect of suture type in repairing different sites of the body such as episiotomy repair, subcutaneous layer repair and skin repair has been studied in various studies. Therefore, in this two-way blind study, the effect of suture type on myometrial repair was investigated in such a way that after randomization, two groups of 25 people, one after cesarean section were sutured with chromic suture and the other group was sutured with vicryl suture. At least 2 months after cesarean section, patients were examined for the incidence of cesarean scar defects (Nich) by a 5MHz Mindrey vaginal ultrasound machine.

Participants/Inclusion and exclusion criteria

Inclusion: Women undergoing cesarean section for the first time Exclusion: history of previous cesarean section, diseases such as diabetes, hypertension, preeclampsia, multiple pregnancies

Intervention groups

A total of 50 women underwent cesarean section were included in the study in terms of inclusion and exclusion criteria and were randomly divided into two groups of 25 based on a table of random numbers. The group that underwent stitching with chromic round 1 thread of Shahid Safai company after cesarean section and the other group underwent suture with vicryl round thread 1 of supk company.

Main outcome variables

The use of chrome thread is associated with more cesarean defects. Therefore, the use of vicryl thread instead of chrome is recommended to reduce the incidence of cesarean scar defects.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210423051055N1**

Registration date: **2021-05-20, 1400/02/30**

Registration timing: **retrospective**

Last update: **2021-05-20, 1400/02/30**

Update count: **0**

Registration date

2021-05-20, 1400/02/30

Registrant information

Name

Mina Rahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3826 2761

Email address

drminarahmani2@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-01, 1399/10/12

Expected recruitment end date

2021-04-01, 1400/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of chromium and vicryl yarn on the extent and severity of cesarean scar defects (nich) in patients undergoing cesarean section

Public title

The relationship between the type of suture used and the incidence and severity of cesarean scar defects (nich)

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Women who have had a cesarean section for the first time

Exclusion criteria:

History of previous cesarean section Having diabetes, high blood pressure and preeclampsia Multiple pregnancies

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 50 women who underwent cesarean section were included in the study in terms of inclusion and exclusion criteria and were randomly divided into two groups of 25 based on a table of random numbers. In this way, after determining the sample size, which included 50 women undergoing cesarean section, 50 codes were prepared and then a random selection by computer was considered a code for each person and we put the code related to each person in front of their name.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, 50 women underwent cesarean section in two groups of 25 people. One group underwent chromium suture after cesarean section and the other group underwent suture with vicryl suture. The study was double-blind and patients and physicians did not know how to group them.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Medical School-Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Shahid Sadoughi Hospital, Ibn Sina Blvd.

City

Yazd

Province

Yazd

Postal code

8915814739

Approval date

2020-09-13, 1399/06/23

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.141

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

cesarean scar defects (nich) in patients with a history of cesarean

ICD-10 code

O34.21

ICD-10 code description

Maternal care for scar from previous cesarean delivery

Primary outcomes**1****Description**

Age

Timepoint

The beginning of the study

Method of measurement

Number of years of life

2**Description**

Type of suture

Timepoint

During a cesarean section

Method of measurement

Type of suture used in cesarean section (chrome / Vicryl)

Secondary outcomes

1

Description

Nich

Timepoint

2 months after cesarean section

Method of measurement

Based on ultrasound findings (yes / no)

2

Description

Cervical dilatation

Timepoint

2 months after cesarean section

Method of measurement

Based on examination and ultrasound findings

Intervention groups

1

Description

Intervention group: After cesarean section, the group underwent sutures with chromic round 1 suture of Shahid Safai Company and after 2 months were examined by Mindrey vaginal ultrasound machine with a frequency of 5 MHz for nich lesions.

Category

Diagnosis

2

Description

Control group: The group that underwent sutures with supa Vicryl Round 1 sutures and after 2 months were examined by Mindrey vaginal ultrasound machine with a frequency of 5 MHz for nich lesions.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Mina Rahmani

Street address

Atlasi 15, Atlasi Street, Safaieh.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Mina Rahmani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

Because of moral issues

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available