Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of NICHE between Continious and Interrupted Methods of Cesarean Incision Repair

Protocol summary

Study aim

The aim of present study is to compare NICHE between continious and interrupted methods of cesarean incision repair.

Design

A clinical trial with two parallel groups without blinding, randomized on 70 pregnant mothers, Rand list software will be used for randomization.

Settings and conduct

70 primigravida women who are undergoing cesarean section in Al-Zahra Educational and Medical Center of Tabriz University of Medical Sciences will be randomly divided into two equal groups (35 people in each group) using a random number table. Cesarean section will be repaired using zero vicryl suture in the first group by continuous method and in the second group by intermittent method. Uterine ultrasound will be done one month after surgery to check the surgical site and NICHE development.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: pregnant women aged 18 to 35 years, primigravida, term pregnancy, candidate for elective cesarean section due to pelvic stenosis or abnormal presentation and BMI between 20 and 25. Exclusion criteria are also: chronic systemic disease, using immunosuppressive drug, history of previous cesarean section, amniotic sac rupture, severe bleeding before surgery and impossibility of proper follow-up after surgery.

Intervention groups

Both groups of mothers will be operated cesarean section surgery by a single surgeon with a pfannenstiel incision under sterile conditions and after spinal anesthesia and receiving prophylactic antibiotics according to the protocol of the obstetrics and gynecology department. Cesarean section repair in both groups will be done using zero vicryl sutures, in the first group the repair will be continuous and in the second group it will be intermittent.

Main outcome variables

The primary outcome of the present study are the existence of NICHE; and the size of NICHE.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121022011205N4**
Registration date: **2021-12-23, 1400/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-23, 1400/10/02**
Update count: **0**

Registration date

2021-12-23, 1400/10/02

Registrant information

Name
Dr.Zahra Fardiazar
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1553 9161
Email address
fardiazar@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of NICHE between Continious and Interrupted Methods of Cesarean Incision Repair

Public title
Comparison of NICHE between Continious and Interrupted Methods of Cesarean Incision Repair
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women aged 18 to 35 years Primigravida Term pregnancy Candidate for elective cesarean section due to pelvic stenosis or abnormal presentation BMI between 20 and 25
Exclusion criteria:
Chronic systemic disease Using immunosuppressants History of previous cesarean section Amniotic sac rupture Severe bleeding before surgery Impossibility of follow-up
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done using Rand list version 1.2 software.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Of Tabriz University Of Medical Sciences
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2019-11-25, 1398/09/04
Ethics committee reference number
IR.TBZMED.REC.1398.885

Health conditions studied

1

Description of health condition studied
Scar of cesarean section on the uterus (NICHE)
ICD-10 code
O34.21
ICD-10 code description
Maternal care for scar from previous cesarean delivery

Primary outcomes

1

Description
Cesarean scar on the uterus (NICHE)
Timepoint
30 to 60 days after surgery
Method of measurement
Uterine ultrasound

Secondary outcomes

1

Description
Infection
Timepoint
After surgery for up to two months after that
Method of measurement
Clinical examination

2

Description
Fever
Timepoint
After surgery for up to two months after that
Method of measurement
Clinical examination

Intervention groups

1

Description
Intervention group1: Repair of cesarean section on the

uterus using VICRYL of supa company (size 0) by continuous method.

Category

Treatment - Surgery

2

Description

Intervention group 2: Repair of cesarean section on the uterus using VICRYL of supa company (size 0) by interrupted method.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Zahra Fardiazar

Street address

Alzahra Hospital, South Artesh St.,Tabriz, iran

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3553 9161

Email

fardyazar@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Dr.Parviz Shahabi

Street address

No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3335 7310

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research,Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Zahra Fardiazar

Position

Professor of Obstetrics and Gynecology

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Tabriz University Of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3553 9161

Email

fardyazar@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Zahra Fardiazar

Position

Professor of Obstetrics and Gynecology

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Tabriz University Of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

009835539161

Email

fardyazar@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Zahra Fardiazar

Position

Professor of Obstetrics and Gynecology

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Tabriz University Of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 35519161

Email

fardyazar@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Not applicable

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

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