

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the outcomes of suture technique with suture fluid adhesion and routine cesarean section

Protocol summary

Study aim

comparative study of the outcomes of suture technique with suture fluid adhesion and routine cesarean section

Design

This study is a non-blinded clinical trial. The study population will be included all women referred to the gynecology ward of Imam Reza hospital Kermanshah Hospital. 32 eligible patients will be selected conveniently and randomly will be assigned into two intervention and control groups.

Settings and conduct

This study which will be conducted in Imam Reza hospital of Kermanshah city is a non-blinded one. After the intervention, both groups will be compared in terms of pain severity and the rate of wound infection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; gestational age greater than or equal to 24 weeks; termination of pregnancy with an elective or emergency cesarean section. Exclusion criteria: BMI > 30; pregnancy with dead fetus; drug abuse; fetal macrosomia; prolonged runoff and coagulopathy

Intervention groups

In the intervention group after the cesarean section, EPIGLU suture adhesive that made in Germany will be used. In the control group, sutures are used as usual.

Main outcome variables

Intensity of pain, Wound infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N134**

Registration date: **2019-12-26, 1398/10/05**

Registration timing: **prospective**

Last update: **2019-12-26, 1398/10/05**

Update count: **0**

Registration date

2019-12-26, 1398/10/05

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1821 4653

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-10, 1398/10/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the outcomes of suture technique with suture fluid adhesion and routine cesarean section

Public title

Comparison of the outcomes of suture technique with suture fluid adhesion and routine cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years gestational age greater than or equal to 24 weeks termination of pregnancy with an elective or emergency cesarean section

Exclusion criteria:

BMI > 30 pregnancy with dead fetus drug abuse fetal macrosomia prolonged runoff and coagulopathy

Age

From 18 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 32

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly by a coin toss

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 Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2019-04-24, 1398/02/04

Ethics committee reference number

IR.KUMS.REC.1398.110

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

cesarean

ICD-10 code

O86.0

ICD-10 code description

Infection of obstetric surgical wound

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

Intensity of pain

Timepoint

End of study

Method of measurement

Asking the patient

2**Description**

Wound infection

Timepoint

End of study

Method of measurement

Doctor observation

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group after the cesarean section, EPIGLU suture adhesive that made in Germany will be used.

Category

Treatment - Devices

2**Description**

In the control group, sutures are used as usual.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Hoda Alsharif

Street address

Emam Reza Hospital, Parastar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
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Building No.2, Shahid Beheshti, Vice Chancellor for
Research Affairs, Kermanshah University of Medical
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fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Hoda Alsharif
Position
Resident of Obstetrics and Gynecology

Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

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

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments