

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effectiveness of topical cefazolin solution versus normal saline in reducing cesarean section infection

Protocol summary

Summary

This is a double-blind, double-blind study that is conducted in Phase 3 trial Studies. It aims to prevent infection and improve wound healing incision cesarean section. The study population is pregnant women admitted to the hospital for cesarean delivery. Inclusion criteria study are pregnant women under 40 years of age and gestational age of more than 37 weeks, without previous underlying illness, have a classic cut (Pfannenstiel incision) of cesarean section during surgery. Patients randomly divided into three groups of 36 people. A total of 108 patients are selected. Assign interventions in each group in parallel. In the first group, patients receive cefazolin solution with normal saline, the second group only receives normal saline and the third group (the control group) does not receive the drug. Then patients are examined on the 5th and 10th days after surgery. The required information and the rate of infection and wound healing (based on REEDA criteria) are collected through by observation and checklist. Then it will be analyzed by statistical software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092436376N1**

Registration date: **2017-10-23, 1396/08/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-23, 1396/08/01

Registrant information

Name

Elaheh Fahimi

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3565 6134

Email address

fahimie89@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Sabzevar University of Medical Sciences

Expected recruitment start date

2017-09-27, 1396/07/05

Expected recruitment end date

2017-10-11, 1396/07/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of topical cefazolin solution versus normal saline in reducing cesarean section infection

Public title

Effect of topical cefazolin on reducing cesarean section infection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: women; Gestational age; Having a living and single fetus; Absence of underlying illness; Classic cesarean section (van Steele); Lack of rupture of the Amniotic sac Exclusion criteria: Women under the age of 18 and over 40 years; Gestational age below 37 weeks; Stillbirth; History of underlying disease;

Addiction; Recent antibiotic use; bleeding more than usual during cesarean section; non-classic cesarean sections; Rupture of the Amniotic sac longer than 18 hours

Age

From **17 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

This is a double-blind trial. Patients accidentally block the block into 3 groups. Assign the groups to study in parallel.

Secondary Ids

empty

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

Sabzevar University of Medical Sciences

Street address

Asad Abadi Street, Central Organization of abzevar
University of Medical Sciences, Sabzevar

City

Sabzevar

Postal code**Approval date**

2017-07-24, 1396/05/02

Ethics committee reference number

IR.MEDSAB.REC.1396.37

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

Infection Caesarean section

ICD-10 code

O86.0

ICD-10 code description

Infection of obstetric surgical wound

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

redness

Timepoint

Days 5 and 10

Method of measurement

Red spot on both sides of the wound

2**Description**

Edama

Timepoint

Days 5 and 10

Method of measurement

Check swelling of the wound and measure to cm

3**Description**

Ecchymosis

Timepoint

Days 5 and 10

Method of measurement

Check ecchymosis of the wound and measure to cm

4**Description**

Discharge

Timepoint

Days 5 and 10

Method of measurement

observation

5**Description**

approximation

Timepoint

Days 5 and 10

Method of measurement

observation

Secondary outcomes**1****Description**

pain

Timepoint

Days 1, 5 and 10

Method of measurement

Measuring the severity of pain based on fatigue from 1 to 5

Intervention groups

1

Description

First group (intervention): Immediately after sewing the fascia, a venous Cefazolin 1000 mg vial with 300 ml of normal saline was washed.

Category

Treatment - Drugs

2

Description

Second group (intervention): Immediately after sewing the fascia with 300 cc normal saline was washed.

Category

Placebo

3

Description

Third group (control): No washing is done (routine method).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahidan Mobini Hospital

Full name of responsible person

Street address

Kashefi Street, Mobini Hospital, Sabzevar, Khorasan Razavi

City

Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Sabzevar University of Medical Sciences

Full name of responsible person

Dr Hamidreza Baghani

Street address

Sabzevar university of Medical Sciences, Sabzevar, Khorasan Razavi

City

Sabzevar

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, Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Behnaz Soeezi

Position

Gynecologist

Other areas of specialty/work

Street address

Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi

City

Sabzevar

Postal code

Phone

+98 51 4401 1000

Fax

Email

Behnazsovizi1355@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Behnaz Soeezi

Position

Gynecologist

Other areas of specialty/work

Street address

Sabzevar University of Medical Sciences, Sabzevar, Khorasan Razavi

City

Sabzevar

Postal code

Phone

+98 51 4401 1000

Fax

Email

Behnazsovizi1355@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Elaheh Fahimi

Position

Medical Student

Other areas of specialty/work

Street address

Sabzevar University of Medical Sciences, Sabzevar,
Khorasan Razavi

City

Feridounkenar

Postal code

Phone

+1 134743164

Fax

Email

fahimi.elaheh@gmail.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty