Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

The effect of the implementation a care bundle for the prevention of caesarean wound infection

Protocol summary

Study aim
The effect of the implementation of the care package for the prevention of caesarean section wound infection

Design
A clinical trial with an intervention and control group, with parallel groups, randomized, was conducted on 60 patients.

Settings and conduct
Patients of the gynecological surgery department are placed in two intervention and control groups. A questionnaire consisting of: patient demographic information form, patient pregnancy information form, patient surgery information form, surgical site infection checklist and REEDA tool.

Participants/Inclusion and exclusion criteria
Entry conditions: not suffering from underlying diseases such as liver/severe kidney disorders/diabetes and severe anemia (Hct<33% or Hb<11g/dl), not using suppressive drugs. immune system (crotons), no history of infectious disease and severe malnutrition in the last 6 months. Conditions of non-entry: hospitalization for more than 1 week after cesarean section, fever above 38 degrees from the time of admission to 48 hours after cesarean section, abnormal bleeding in one month leading to termination of pregnancy.

Intervention groups
The intervention group will be the recipients of the care package for the prevention of surgical site infection, so that pre-surgery care will be provided to the patients according to the care package. The control group will receive all the usual and routine care of the surgical department and the operating room, and the examination of the surgical incision in terms of signs of infection is similar to the intervention group, in the first 24 hours and after removing the dressing, at each time of washing the wound and the time of suture removal and day. It will be done on the 30th.

Main outcome variables
wound infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170703034873N3**
Registration date: **2022-10-09, 1401/07/17**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-09, 1401/07/17**
Update count: **0**

Registration date
2022-10-09, 1401/07/17

Registrant information

Name
fariba Yaghoubinia

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of the implementation a care bundle for the prevention of caesarean wound infection

Public title
The effect of the implementation a care bundle for the prevention of caesarean wound infection

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Candidates for non-emergency cesarean section due to obstetric and non-obstetric indications Patient consent to participate in the study Being at least 18 years old singleton pregnancy Gestational age greater than or equal to 37 weeks Not suffering from an underlying disease such as severe liver/kidney disorders/diabetes and severe anemia (Hct<33% or Hb<11g/dl) Not using immunosuppressive drugs (cortones) No history of infectious disease and severe malnutrition in the last 6 months The patient's BMI should be less than 35 Failure to detect placenta accreta or placenta previa in ultrasound before caesarean section

Exclusion criteria:
Hospitalization for more than 1 week after cesarean section Receiving blood products within the last 10 days Fever above 38 degrees from the time of admission to 48 hours after cesarean section Not being discharged from the first 24 hours after surgery due to the presence of any birth complications Non-referral in the one-month follow-up of the patient

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be selected using the available sampling method, using the research unit's selection checklist and based on the criteria for entering the study and among women candidates for non-emergency caesarean section. Then they will be assigned to two intervention and control groups by random allocation method and using permutation blocks. Considering that two groups are considered in the study, patients are allocated in 6 cases of blocks of four, A is the intervention group (receiving a preventive care package from surgical site infection) and B is the control group, for example (AABB, ABAB, BBAA,...), in each block, there will be two people from each group. The order of the blocks will be determined randomly using a table of random numbers, and then the patients will be divided into two intervention and control groups based on the blocks.

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 Zahedan University of Medical Sciences

Street address
Zahedan, Zahedan University of Medical Sciences and Medical Services campus administrative complex, Khaleej Fars Blvd.

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Approval date
2022-08-28, 1401/06/06

Ethics committee reference number
IR.ZAUMS.REC.1401.176

Health conditions studied

1

Description of health condition studied
The effect of the implementation of the care package for the prevention of caesarean section wound infection

ICD-10 code
O86.0

ICD-10 code description
Infection of obstetric surgical wound

Primary outcomes

1

Description
caesarean section wound infection

Timepoint
For patients, pre-surgery care will be provided according to the care package, after the patient is called to the operating room, intra-operative care will be provided, and after the surgery, post-surgery care will be provided in the recovery room and women's surgery department.

Method of measurement
Data collection tool The data collection tool in this study is a questionnaire consisting of four sections A: Patient demographic information form B: Patient pregnancy information form C: Patient surgery information form and

surgical site infection checklist and REEDA tool will be.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The recipient of the infection prevention care package will be the operation site, so that pre-surgery care will be provided for patients according to the care package, after the patient is called to the operating room, intra-operative care will be provided, and after the surgery, post-surgery care will be provided. It will be done in the recovery room and women's surgery department. To confirm or rule out wound infection, 24 hours after the operation and every dressing change (as long as the patient is in the inpatient ward) and on the eighth day after surgery (when the sutures are removed), check the wound for the occurrence of infection using a check list. The wound and the REEDA tool will be performed. Basically, the patient's surgical incision will be observed by the researcher (surgeon and nurse) after removing the wound dressing and before using the wound washing solutions, and after completing the wound examination checklist, washing and dressing the wound is done According to the discharge of the patients, for the 30-day post-surgery review, the symptoms of wound infection will be taught to the patients, and a checklist will be given to the patients to complete the training provided about the surgical wound and On the thirtieth day, when the patient is visited again by the researcher at the women's clinic or home, present it to the researcher. The researcher will contact the patients from the time of discharge until 30 days after the surgery and will provide the necessary explanations on how to care for the wound and remind the patient to complete the checklist. Regarding the implementation of the care package, of course, not all cases can be done by the researcher, especially care during surgery, but the correct implementation of the package in these cases will be under the supervision of the researcher.

Category

Prevention

2

Description

Control group: First, demographic, pregnancy and surgical information will be collected through interview and patient file study, and they will receive all the usual and routine care of the surgical department and operating room, and the examination of the surgical incision in terms of signs of infection is similar to the intervention group, in the first 24 hours and After removing the dressing, the wound is washed every time and when the stitches are removed and on the 30th day. The data collection method will be using the information recorded in the patient's hospital record and directly observing the wound and completing the checklist. If the patient has signs of redness, clear swelling more than 0.5 cm from the opening of the wound, local pain or pain when touching, increased heat. Around the wound, there was an increase in body temperature of more than 37.7 degrees Celsius with or without chills, purulent secretions or a bad smell from the wound, this wound is considered infected. The 30th day will be the end of the study period of the implementation of the care package in the intervention group, and of course the control group will also be examined in the same time period. Each patient will be monitored for one month after surgery. A pamphlet containing the symptoms of wound infection along with education will be given to the patients during discharge so that they can refer to them if any of the symptoms of infection occur.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

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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
Zahedan 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

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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
There is no further information.
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
No - There is not a plan to make this available
Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available