Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

The study of comparsion effect of closure versus non-closure of the peritoneum on Maternal Short-Term Complications at elective and Emergency cesarean section

Protocol summary

Study aim
comparsion effect of closure versus non-closure of the peritoneum on Maternal Short-Term Complications at elective and Emergency cesarean section

Design
A clinical trial study with parallel and double-blind groups, in which 84 patients were randomly assigned to two groups of intervention and control by lottery technique. In this study, the mothers and the person who evaluates the outcome are blinded by lack of knowledge of the peritoneum restoration method.

Settings and conduct
A study was conducted on 84 pregnant women who referred to Fatemiyeh Hospital in Hamedan for cesarean section.There are 42 patients in the control group (21 with elective cesarean section and 21 with emergency cesarean section) which they are surgically treated with the technique of closure the peritoneum And 42 others in the intervention group (21 with elective cesarean section and 21 with emergency cesarean section) which they are surgically treated with the technique of non-closure the peritoneum. All of this 84 cesarean section is done by a surgeon. The study variables are monitoring during and after surgery.

Participants/Inclusion and exclusion criteria
The age range of mothers is 18-40 years old ؛ Not having chronic disease like diabetes ؛ Not having drug addiction

Intervention groups
in control group the visceral and parietal peritoneum is closure routinely bout in the intervention group visceral and parietal peritoneum non-closure.

Main outcome variables
pain, infection, hemorrhage, fever, Ileus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181211041932N2**
Registration date: **2019-03-30, 1398/01/10**
Registration timing: **prospective**

Last update: **2019-03-30, 1398/01/10**
Update count: **0**

Registration date
2019-03-30, 1398/01/10

Registrant information

Name
Shirdel Zandi Charkhebayan

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 87 5854 7427

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-09, 1398/01/20

Expected recruitment end date
2019-06-10, 1398/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The study of comparsion effect of closure versus non-

closure of the peritoneum on Maternal Short-Term Complications at elective and Emergency cesarean section

Public title
The study of comparsion effect of closure versus non-closure of the peritoneum on Maternal Short-Term Complications at elective and Emergency cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The age range of mothers is 18-40 years old Not having chronic disease like diabetes Not having drug addiction

Exclusion criteria:
Having previous laparotomy history Unwillingness to work with a researcher

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Using available sampling, patients are divided into two layers of elective cesarean section and emergency cesarean section. In each layer, a randomized simple method is used to select the peritoneal repair method for each patient, In this way, using the lottery, the first cesarean will be surgically treated with one of the two techniques of closure or non-closure of the peritoneum and the next patient with the opposite technique, This method continues to complete the number of samples of both groups in each of the layers.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double blind study, participants and outcome evaluators are blinded to the division of subjects into study groups. To keep the participants blind: At the beginning of the study, we will explain the purpose of the study for them and we will describe two different methods of repairing the peritoneum. But the details of the method that used for each patient are not explained. To keep the outcome evaluators blind: The surgical procedure information is only recorded in the patient's surgical record and outcome evaluators dont have access to information.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Hamedan University of Medical Sciences

Street address
Shahid Fahmidah Street, Hamedan University of Medical Sciences and Health Services

City
Hamedan

Province
Hamadan

Postal code
65178

Approval date
2019-03-09, 1397/12/18

Ethics committee reference number
IR.UMSHA.REC.1397.962

Health conditions studied

1

Description of health condition studied
caesarean section

ICD-10 code
O82

ICD-10 code description
Single delivery by caesarean section

Primary outcomes

1

Description
Hemorrhage

Timepoint
During surgery and after surgery

Method of measurement
Measuring the volume of blood in the suction AND the weight of blood-stained gases during surgery AND Measuring dressing weight when changing after surgery.

2

Description
Pain

Timepoint
2-4-12-24 hours after surgery

Method of measurement
Use the pain Visual Analogue Scale (VAS)

3

Description

Fever
Timepoint
2-4-12-24 hours after surgery
Method of measurement
use of Medical Thermometer

4

Description
Infection
Timepoint
A week after surgery
Method of measurement
Patient file information

5

Description
Ileus
Timepoint
after surgery
Method of measurement
Intestinal sounds, The first time the Stool

Secondary outcomes

empty

Intervention groups

1

Description
Control group: in control group the visceral and parietal peritoneum is closure
Category
Treatment - Surgery

2

Description
Intervention group: in the intervention group visceral and parietal peritoneum non-closure.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital Hamedan
Full name of responsible person
Shohreh Alimohamadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All personal data is shared after unidentifiable people.Includes demographic data and data related to study variables.
When the data will become available and for how long
The data is shared three months after the publication of the results
To whom data/document is available
All researchers can take data.
Under which criteria data/document could be used
The data is provided under the condition that First, they have a clear purpose for using the data. Secondly, the source of data should be mentioned wherever these data are to be used
From where data/document is obtainable
can use the following e-mail address to receive the data. liondelzandii@gmail.com
What processes are involved for a request to access data/document
After sending the request to the e-mail address, the data will be sent in time.
Comments