

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

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

Protocol summary

Study aim

comparison 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 but 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 Charkhebyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 5854 7427

Email address

liondelzandii@gmail.com

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 comparison 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 comparison 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
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
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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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Person responsible for updating data

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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