

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of hospitalization time after elective cesarean section on maternal complications

Protocol summary

Study aim

Determining the effect of hospitalization time after elective cesarean section on maternal complications

Design

This study is a randomized clinical trial that will be performed on 294 women who undergo elective cesarean section surgery in the Gynecology ward of Imam Sajjad Hospital in Yasuj, Iran during 2018-2019.

Settings and conduct

Group A (hospitalization after cesarean for 24 hours) and group B (hospitalization after cesarean section for 48 hours). In both groups, during the first 24 hours, an intravenous antibiotic of cefazolin and pethidine intake will be prescribed at the time of pain. Patients will be discharged from the hospital with the hematinic and mefenamic acid.

Participants/Inclusion and exclusion criteria

Age less than 35, elective cesarean in previous pregnancy, non-underlying diseases such as immune system, diabetes, high blood pressure, heart disease, pulmonary and blood diseases, severe non-hemorrhage during surgery, no specific drug, single pregnancy, maternal BMI according weight before pregnancy under 30.

Intervention groups

Hospitalization after cesarean delivery for 24 hours compared to 48 hours.

Main outcome variables

cesarean site infection, separation of incision, endometritis, urinary tract infection, digestive complications, lactation, pain and satisfaction of the patient after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160524028038N3**

Registration date: **2019-05-30, 1398/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-30, 1398/03/09**

Update count: **0**

Registration date

2019-05-30, 1398/03/09

Registrant information

Name

Fatemeh Bazarganipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3366 6367

Email address

bazarganipour@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-19, 1397/11/30

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hospitalization time after elective cesarean section on maternal complications

Public title

The effect of hospitalization time after elective cesarean section on maternal complications

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age less than 35 Elective cesarean section in previous pregnancy Non-underlying diseases such as immune deficiency, diabetes, high blood pressure, heart disease, pulmonary and blood disorders Severe non-hemorrhage during surgery Non-use of special drug Single pregnancy Maternal BMI according to weight before pregnancy below 30

Exclusion criteria:

Lack of follow-up Unwillingness to participate in the study

Age

To 35 years old

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**

Target sample size: 294

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is simple. The sealed envelopes were used.

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 Yasuj University of Medical Sciences

Street address

• No. 7916839319, Shahid Jalil Ave., Yasuj Town, kohgiluyeh and boyer-ahmad

City

yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7916839319

Approval date

2019-01-05, 1397/10/15

Ethics committee reference number**Health conditions studied****1****Description of health condition studied**

cesarean section

ICD-10 code

O82.8

ICD-10 code description

Other single delivery by caesarean section

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

incision infection

Timepoint

one and six weeks after discharge

Method of measurement

questionnaire

2**Description**

separation of incision

Timepoint

one and six weeks after discharge

Method of measurement

questionnaire

3**Description**

Endometritis

Timepoint

one and six weeks after discharge

Method of measurement

questionnaire

4**Description**

urinary tract infection

Timepoint

one and six weeks after discharge

Method of measurement

questionnaire

5**Description**

Digestive complications

Timepoint

one and six weeks after discharge

Method of measurement

questionnaire

6

Description

Lactation

Timepoint

one and six weeks after discharge

Method of measurement

questionnaire

7

Description

Postoperative pain

Timepoint

one and six weeks after discharge

Method of measurement

questionnaire

8

Description

postoperative satisfaction

Timepoint

one and six weeks after discharge

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Hospitalization after cesarean section for 24 hours

Category

Treatment - Other

2

Description

Control group: Hospitalization after cesarean section for 48 hours

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yasuj University of Medical Sciences

Full name of responsible person

Leila Jamali

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No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

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leilajml1389@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Hossein Mari-Oriad

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No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

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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

Yasuj 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

Yasuj University of Medical Sciences

Full name of responsible person

Leila Jamali

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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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

No more 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