Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of suppository indomethacin and combination of indomethacin- acetaminophen on post operative pain after cesarean section

Protocol summary

Summary

Aim: Comparison of suppository indomethacin and combination of indomethacin- acetaminophen on post operative pain after cesarean section. In this study, 76 pregnant women undergoing elective cesarean section at Imam Reza hospital in Kermanshah are assessed. Inclusion criteria include elective cesarean section with lower uterine segment incision; pregnancy over 37 weeks. Patients are randomized to one of two groups: Group A: A 50-mg indomethacin rectal suppository is administered immediately after the cesarean every 6 hours for 24 hours after the operation. Group B: Two rectal suppositories (A 50-mg indomethacin and a 325-mg acetaminophen) are administered immediately after cesarean every 6 hours for 24 hours after the operation. Women randomized into two groups by 1:1 ratio method using a computer-generated random numbers. Variables consist pain, nausea and vomiting, need for analgesic and anti-emetic drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042013069N1**
Registration date: **2013-09-22, 1392/06/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-09-22, 1392/06/31

Registrant information

Name

Mohammad Rasoul Ghadami

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1427 6310

Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-03-06, 1391/12/16

Expected recruitment end date

2013-06-05, 1392/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of suppository indomethacin and combination of indomethacin- acetaminophen on post operative pain after cesarean section

Public title

Suppository indomethacin and combined indomethacin-acetaminophen for pain after cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria include elective cesarean section with lower uterine segment incision; pregnancy over 37 weeks. Exclusion criteria include anemia, multiple pregnancies, poly hydramnious, prolonged labor, premature rupture of membranes, diabetes, high blood

pressure, renal disease, history of drug abuse or smoking, cardiovascular diseases and coagulation disorders. or other underlying diseases.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Women randomized into two groups by 1:1 ratio using a computer-generated random numbers. Physician who evaluates the pain is blind to treatment interventions.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Kermanshah University of Medical Sciences

Street address

Shahid beheshti Blvd. Build no. 2

City

Kermanshah

Postal code

Approval date

2013-03-05, 1391/12/15

Ethics committee reference number

420/7/643/پ

Health conditions studied

1

Description of health condition studied

Post-cesarean pain

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

Pain severity

Timepoint

2, 4, 6, 12, 24 h after operation

Method of measurement

VAS with a 10-cm ruler is used and patient shows her pain on the ruler.

Secondary outcomes

1

Description

Nausea and vomiting, need for analgesic and anti-emetic

Timepoint

2, 4, 6, 12, 24 h after operation

Method of measurement

Ask from patient by resident

Intervention groups

1

Description

Group A: A 50-mg indomethacin rectal suppository is administered immediately after a cesarean every 6 hours for 24 hours after the operation.

Category

Treatment - Drugs

2

Description

Group B: Two rectal suppositories (A 50-mg indomethacin and a 325-mg acetaminophen) are administered immediately after cesarean every 6 hours for 24 hours after the operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Street address

Sorkheh lizheh

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences, Vice chancellor for research

Full name of responsible person

Dr. Farid Najafi

Street address

Vice chancellor for research, Build no. 2, Shahid Beheshti Blvd.

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences, Vice chancellor for research

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rasoul Ghadami

Position

General physician

Other areas of specialty/work

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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