

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 83 1427 6310

##### Email address

mrghadami@kums.ac.ir

##### 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**

Sorkkeh 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****Street address**

Imam Reza hospital, Sorkheh lizheh

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mrghadami@kums.ac.ir  
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### Person responsible for scientific inquiries

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**Position**

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### Person responsible for updating data

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### 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*