

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Feb 2026

### The effects of diclofenac suppository and intravenous acetaminophen, and the combination of them, on postoperative pain in patients undergoing spinal anesthesia for cesarean section

#### Protocol summary

##### Summary

This study is to evaluate of the effects of diclofenac suppository and intravenous acetaminophen, and the combination of them on postoperative pain in patients undergoing spinal anesthesia for cesarean section. Objectives: To investigate the effect of diclofenac suppository and Intravenous acetaminophen and the combination of them on the severity of postoperative pain in patients undergoing spinal anesthesia for cesarean section in Sayyad Shirazi health education center of Gorgan in 1393. Design: This study is randomized, double-blind. Setting and conduct: 90 patients scheduled for cesarean surgery will be randomly divided into three groups: A. 100 mg diclofenac suppositories, B.1000 mg intravenous acetaminophen, and C.50 mg of diclofenac suppositories and 500 mg intravenous acetaminophen. In the recovery, based on severity of pain measured by visual analogue scale (VAS), if the patients have moderate pain medication will be given. Main inclusion criterion: ASA class of 1 and 2, term gestational age. Main exclusion criteria: any allergies to medications such as acetaminophen and local anesthetics, liver and kidney diseases and diabetes. Interventions: Assessment of pain severity at 0, 2, 4, 6, 12, 24 and administration of nonsteroidal anti-inflammatory drug in three groups according to their average pain severity measured by (VAS). Main outcome measures: determination of pain severity in the groups.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT201205099697N1**  
Registration date: **2015-01-27, 1393/11/07**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-01-27, 1393/11/07

##### Registrant information

###### Name

Fozieh Bakhsha

###### Name of organization / entity

Golestan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 3253 8011

###### Email address

bakhsha@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology, Golestan University of Medical Sciences

##### Expected recruitment start date

2014-04-03, 1393/01/14

##### Expected recruitment end date

2015-05-04, 1394/02/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effects of diclofenac suppository and intravenous acetaminophen, and the combination of them, on postoperative pain in patients undergoing spinal anesthesia for cesarean section

**Public title**

Assessment of the effects of diclofenac suppository and intravenous acetaminophen, and the combination of them, on postoperative pain in patients undergoing spinal anesthesia for cesarean section

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients with 1 and 2 ASA class of Anesthesia; Term gestational age; absence of chronic diseases such as cardiovascular; hepatic and renal disease. exclusion criteria: hypersensitivity to any drug such as acetaminophen; local anesthetics, having liver or renal disease; diabetes, and patients who used analgesic drugs (opioids, NSAID and corticosteroid) within 8 to 12 hours before the intervention

**Age**

From **17 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Samples receiving medicine will be divided into three groups with simple random sampling method.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Golestan University Of Medical Sciences

**Street address**

km 4 road Sari Gorgan, Vice Chancellor for Research and Technology, Golestan University of Medical Sciences, Gorgan, Golestan province, Iran

**City**

Gorgan

**Postal code**

49341-74515

**Approval date**

2014-03-02, 1392/12/11

**Ethics committee reference number**

36439212016

**Health conditions studied****1****Description of health condition studied**

Acute Pain

**ICD-10 code**

R52.0

**ICD-10 code description**

Acute Pain

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

Determination of pain severity before intervention in patients undergoing spinal anesthesia for cesarean section in diclofenac suppository group in Sayyad Shirazi Hospital of Gorgan

**Timepoint**

before intervention

**Method of measurement**

Visual Analogue Scale (VAS)

**2****Description**

Determination of pain severity before intervention in patients undergoing spinal anesthesia for cesarean section in intravenous acetaminophen group in Sayyad Shirazi Hospital of Gorgan

**Timepoint**

before intervention

**Method of measurement**

Visual Analogue Scale(VAS)

**3****Description**

Determination of pain severity before intervention in patients undergoing spinal anesthesia for cesarean section in combination of the intravenous acetaminophen and diclofenac suppository group in Sayyad Shirazi Hospital of Gorgan

**Timepoint**

before intervention

**Method of measurement**

Visual Analogue Scale (VAS)

**4****Description**

Determination of pain severity after intervention in patients undergoing spinal anesthesia for cesarean section in group of diclofenac suppository in Sayyad Shirazi Hospital of Gorgan

**Timepoint**

in hour 0, 2, 4, 6, 12, 24

## Method of measurement

Visual Analogue Scale

## 5

### Description

Determination of pain severity after intervention in patients undergoing spinal anesthesia for cesarean section in group of intravenous acetaminophen in Sayyad Shirazi Hospital of Gorgan

### Timepoint

in hour 0, 2, 4, 6, 12,24

### Method of measurement

Visual Analogue Scale (VAS)

## 6

### Description

Determination of pain severity after intervention in patients undergoing spinal anesthesia for cesarean section in combination of the intravenous acetaminophen and diclofenac suppository group in Sayyad Shirazi Hospital of Gorgan

### Timepoint

in hour 0, 2, 4, 6, 12, 24

### Method of measurement

Visual Analogue Scale (VAS)

## 7

### Description

Comparison of pain severity after the intervention in patients undergoing spinal anesthesia for cesarean section groups of acetaminophen, diclofenac, and the combined intravenous acetaminophen and diclofenac suppository in Sayyad Shirazi Hospital of Gorgan

### Timepoint

in hour 0, 2, 4, 6, 12, 24

### Method of measurement

Visual Analogue Scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Diclofenac suppositories 100 mg, based on average pain severity of patients evaluated at Hour 0, 2, 4, 6, 12, 24 after local anesthetic in the recovery unit, will be prescribed. Aboureihan Pharmaceutical product

#### Category

Treatment - Drugs

### 2

#### Description

intravenous acetaminophen 1000mg, based on average pain severity of patients evaluated at Hour 0, 2, 4, 6, 12, 24 after local anesthetic in the recovery unit, will be

prescribed. Daroupakhsh Pharmaceutical product

#### Category

Treatment - Drugs

### 3

#### Description

Combination of diclofenac suppository 100 mg and 500 mg intravenous acetaminophen, based on average pain severity of patients at hour 0, 2, 4, 6, 12, 24 post-local anesthetic in recovery unit, will be prescribed.

Aboureihan and DarouPakhsh pharmaceutical products

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sayyad Shirazi Hospital of Gorgan

##### Full name of responsible person

Fozieh Bakhsha, MSc Anesthesiology, Academic staff Instructor, Director of Department Anesthesiology

##### Street address

Department of Anesthesiology, Faculty of Paramedical Sciences, Golestan University of Medical Sciences, Km 4 road Sari-Gorgan, Gorgan, Golestan province, Iran n

##### City

Gorgan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Golestan University of Medical Sciences

##### Full name of responsible person

Masoud khoshnia, Director of Vice Chancellor Research and Technology

##### Street address

Vice Chancellor for Research and Technology, Golestan University of Medical Sciences, km 4 road Sari Gorgan, Gorgan, Golestan province, Iran

##### City

Gorgan

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Golestan University of Medical Sciences

#### 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**

Golestan University of Medical Sciences

**Full name of responsible person**

Fozieh Bakhsha

**Position**

MSc in Anesthesia, Instructor of Paramedical School

**Other areas of specialty/work****Street address**

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Fozieh Bakhsha

**Position**

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**Other areas of specialty/work****Street address**

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**City**

Gorgan

**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*