

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison of the Effect of Diclofenac Suppositories and Intravenous Paracetamol in Postoperative Pain

#### Protocol summary

##### Summary

Back ground: the cesarean section is one of the most common surgical procedures that is more prevalent in Iran than Western societies. One of the complications of after cesarean section is the pain after surgery that , if not controlled properly, impairs communication between the mothers and their babies causing an unpleasant feeling. The acute pain control after cesarean is of great importance. Regarding the importance of pain control, there is an attempt in this research to compare the effects of two common non-narcotic medications to have a better control over acute pain after cesarean. Method: This study is a clinical trial. In this study, 88 patients with ASA class I and II at the age of 15-45 who underwent cesarean were selected. 100 mg diclofenac suppository for the first group and 1g of acetaminophen IV in 100 ml normal saline for the second group were repeated immediately after measurement and over 24 hours. The control of postpartum hemorrhage can be assessed by clinical examination, postoperative Hb 6-12 hours after surgery and Pad Score. Major outcome measures are postoperative pain and bleeding

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016081829414N1**

Registration date: **2016-12-13, 1395/09/23**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-12-13, 1395/09/23

##### Registrant information

###### Name

Vahideh Rashtchi

##### Name of organization / entity

Zanjan university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 341 1683

##### Email address

rashtchi@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Zanjan University of Medical Sciences

##### Expected recruitment start date

2016-12-21, 1395/10/01

##### Expected recruitment end date

2017-03-19, 1395/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effect of Diclofenac Suppositories and Intravenous Paracetamol in Postoperative Pain

##### Public title

the Effect of Diclofenac Suppositories on postoperative pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: ASA class I,II; age between 15-45 years old; candidate for emergent or elective cesarean section with spinal anesthesia. Exclusion criteria: when NSAIDS are contraindicated; morbid obesity; HTN; history of cardiovascular, respiratory, coronary artery, renal, gastrointestinal, neuromascular and liver diseases;

diabetes; coagulopathy; patients refusal; abnormal bleeding; infection in the site of spinal anesthesia.

### Age

From **15 years** old to **45 years** old

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **88**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### 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

Zanjan University of Medical Sciences

##### Street address

Zanjan University of Medical Sciences, Azadi blvd.

##### City

Zanjan

##### Postal code

#### Approval date

2015-02-06, 1393/11/17

#### Ethics committee reference number

ZUMS.REC.1393.197

## Health conditions studied

### 1

#### Description of health condition studied

postoperative pain

#### ICD-10 code

XXI

#### ICD-10 code description

XXI Factors influencing health status and contact with health services

## Primary outcomes

### 1

#### Description

Postoperative pain

#### Timepoint

6, 12, 18 and 24 hours after operation

#### Method of measurement

visual analogue scale

## Secondary outcomes

### 1

#### Description

Postoperative bleeding

#### Timepoint

6 and 12 hours after operation

#### Method of measurement

Pad score

## Intervention groups

### 1

#### Description

In one group 100 mg diclofenac suppository immediately after operation and repeat over 6 hours.

#### Category

Treatment - Drugs

### 2

#### Description

In the other group 1g of acetaminophen IV in 100 ml normal saline administered immediately and every 6 hours for 24 hours.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Musavi hospital

##### Full name of responsible person

Dr. Behnaz Molaei

##### Street address

Ayatollah Musavi hospital, Gavazang road

##### City

Zanjan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanjan University of Medical Sciences

##### Full name of responsible person

Dr Alireza Shogli

**Street address**

Zanjan University of Medical Sciences, Azadi blvd.

**City**

Zanjan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Behnaz Molaei

**Position**

Gynecologist

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

Ayatollah Musavi hospital, Gavazang Road

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+98 24 3313 0000

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Molaei@zums.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Vahideh Rashtchi

**Position**

Anesthesiologist

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Vahideh Rashtchi

**Position**

Anesthesiologist

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

Azadi Avenue

**City**

Zanjan

**Postal code****Phone****Fax****Email****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*