

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison the effect of Diclofenac NA and hydrocortisone on shivering in patients undergoing cesarean section under spinal anesthesia

#### Protocol summary

##### Summary

The aim of this study is the comparison of Diclofenac NA suppository and intravenous hydrocortisone on shivering after cesarean section surgery. Design: It is a double-blind randomized clinical trial study in Kowsar teaching hospital. Setting and conduct: aforementioned drugs administered 10 minutes before spinal anesthesia and tympanic temperature, mean arterial pressure, pulse rate and shivering severity will be recorded 10 minute before intrathecal injection in recovery room, at the end of operation and every 30 minutes until 1 hour. Participants: 150 physical status 1 pregnant women, scheduled for elective cesarean section enroll in this study and they will be excluded if they have a history of asthma; peptic ulcer; renal, hepatic or hemorrhagic diseases. Interventions: First group receive Diclofenac NA suppository and normal saline, second group receive intravenous Hydrocortisone and placebo suppository and third group receive intravenous normal saline and placebo suppository. Main outcome measure variable: Shivering

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201602273051N6**

Registration date: **2016-09-20, 1395/06/30**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-20, 1395/06/30

##### Registrant information

##### Name

Marzieh Khezri

##### Name of organization / entity

Qazvine University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 1223 6376

##### Email address

mkhezri@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research, Qazvin University of Medical Science and Health Services

##### Expected recruitment start date

2016-09-05, 1395/06/15

##### Expected recruitment end date

2017-01-04, 1395/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of Diclofenac NA and hydrocortisone on shivering in patients undergoing cesarean section under spinal anesthesia

##### Public title

The effect of Diclofenac NA and hydrocortisone on shivering

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: pregnant women who candidate for elective cesarean section; ASA class 1, 2. Exclusion criteria: history of asthma; peptic ulcer; febrile disease, or endocrine disease; addiction to opioid; smoking; consumption of steroids; consumption of NSAIDS or other analgesics.

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **150**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

##### Street address

Bahonar Blvd, Qazvin, Iran

##### City

Qazvin

##### Postal code

#### Approval date

2013-11-25, 1392/09/04

#### Ethics committee reference number

28/20/8104

## Health conditions studied

### 1

#### Description of health condition studied

Complications predominantly related to the anesthesia

#### ICD-10 code

089.5

#### ICD-10 code description

Other complications of spinal and epidural anaesthesia

## Primary outcomes

### 1

#### Description

shivering

## Timepoint

10 min before anesthesia, after surgery and every 30 minute until an hour.

## Method of measurement

observation and medical records

## Secondary outcomes

### 1

#### Description

Temperature

#### Timepoint

10 min before anesthesia, after surgery and every 30 minute until one hour

#### Method of measurement

Thermometry from tympanic membrane

### 2

#### Description

Blood pressure

#### Timepoint

10 min before anesthesia, after surgery and every 30 minute until one hour

#### Method of measurement

With manometry from brachial artery

### 3

#### Description

Pulse rate

#### Timepoint

10 min before anesthesia, after surgery and every 30 minute until one hour

#### Method of measurement

With monitoring

## Intervention groups

### 1

#### Description

Intervention 1: First group receive placebo Supp. and 2cc of IV hydrocortison, 10 min before anesthesia.

#### Category

Prevention

### 2

#### Description

Intervention 2: Second group receive 100mg Diclofenac supp and 2cc of normal saline, 10 min before anesthesia

#### Category

Prevention

### 3

#### Description

Intervention 3: Third group receive placebo Supp and 2cc of IV normal saline, 10 min before anesthesia .

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Kowsar Hospital

**Full name of responsible person**

Dr. Marziyeh Beigom Khezri

**Street address**

Kowsar Hospital, Taleghani street, Qazvin, Iran

**City**

Qazvin

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Qazvin University of  
Medical Sciences

**Full name of responsible person**

Dr. Naser Taghipoor Farivar

**Street address**

Bahonar Blvd, Qazvin, Iran

**City**

Qazvin

**Grant name**

-

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice Chancellor for Research of Qazvin 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**

Kowsar Hospital

**Full name of responsible person**

Dr. Marziyeh Beigom Khezri

**Position**

Associate Professor/ Anesthesiologist

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

Kowsar Hospital, Taleghani street, Qazvin, Iran

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

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**Full name of responsible person**

Dr. Marziyeh Beigom Khezri

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

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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*