

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison study of combined Diclofenac NA and hydrocortisone versus Diclofenac or hydrocortisone on shivering and pain during cesarean section under spinal anesthesia

#### Protocol summary

##### Summary

The aim of this study is the comparison of combined Diclofenac NA suppository and intravenous hydrocortisone versus with Diclofenac NA suppository or intravenous hydrocortisone on shivering and pain during cesarean section surgery. It is a double-blind randomized clinical trial study on 150 women who were candidate for elective cesarean. 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. First group received Diclofenac NA suppository and normal saline, second group received intravenous Hydrocortisone and placebo suppository and third group received intravenous Hydrocortisone and Diclofenac NA suppository. Thermometry from tympanic membrane was done 10 min before anesthesia, after surgery and every 30 minute until an hour. Pain severity is classified in numerical scale in 24 hours and analgesic administered if needed and the earliest time that analgesic administered and total dose of analgesic in 24 hours compare with each other.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014041317136N2**  
Registration date: **2014-06-12, 1393/03/22**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-06-12, 1393/03/22

#### Registrant information

##### Name

Seyed Ali Hosseini

##### Name of organization / entity

Qazvin University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3368 3980

##### Email address

sahoseini@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

2013-12-22, 1392/10/01

#### Expected recruitment end date

2014-10-23, 1393/08/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison study of combined Diclofenac NA and hydrocortisone versus Diclofenac or hydrocortisone on shivering and pain during cesarean section under spinal anesthesia

#### Public title

Comparison study of combined Diclofenac NA and hydrocortisone versus Diclofenac or hydrocortisone on shivering and pain during cesarean section under spinal anesthesia

## 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

No age limit

## 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

Qazvin university of medical science

##### Street address

Shahid Bahonar Blv

##### City

Qazvin

##### Postal code

3418899581

#### 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 puerperium

#### ICD-10 code

089.5

## ICD-10 code description

Other complications of spinal and epidural anaesthesia during the puerperium

## Primary outcomes

### 1

#### Description

Shivering

#### Timepoint

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

#### Method of measurement

Vision and medical records

### 2

#### Description

Pain

#### Timepoint

Until 24 hours post operation

#### Method of measurement

The first time and the total dose of analgesic administered

## Secondary outcomes

### 1

#### Description

Temperature

#### Timepoint

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

#### Method of measurement

Thermometry from tympanic membrane

### 2

#### Description

Blood pressure

#### Timepoint

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

#### Method of measurement

With monitoring

## Intervention groups

## 1

### Description

Second group received plasebo Supp. and 2cc of IV hydrocortison

### Category

Treatment - Drugs

## 2

### Description

First group received 100mg Diclofenac supp and 2cc of normal saline

### Category

Treatment - Drugs

## 3

### Description

Third group received 100 mg diclofenac Supp. and 2cc of IV hydrocortison

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kosar hospital

##### Full name of responsible person

Dr. Marzieh Beigom Khezri

##### Street address

Taleghani street,Kosar Hospital

##### City

Qazvin

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

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

##### Full name of responsible person

Dr Saeed Assefzadeh

##### Street address

Shahid Bahonar Blvd

##### 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, Qazvin University of Medical Science and Health Services

#### 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

Kosar Hospital

#### Full name of responsible person

Dr. Marzieh Beigom Khezri

#### Position

Anesthesiologist

#### Other areas of specialty/work

#### Street address

Taleghani street

#### City

Qazvin

#### Postal code

3418899581

#### Phone

+98 28 3222 2452

#### Fax

#### Email

mkhezri@qums.ac.ir; sahoseine@qums.ac.ir

#### Web page address

qums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kosar Hospital

#### Full name of responsible person

Dr. Marzieh Beigom Khezri

#### Position

Anesthesiologist/assistant professor

#### Other areas of specialty/work

#### Street address

Taleghani street,Kosar Hospital

#### City

Qazvin

#### Postal code

3418899581

#### Phone

+98 28 3222 2452

#### Fax

#### Email

mkhezri@qums.ac.ir,sahoseini@qums.ac.ir

#### Web page address

www.qums.ac.ir

## Person responsible for updating data

### Contact

#### Name of organization / entity

Kosar Hospital

**Full name of responsible person**

Dr. Marzieh Beigom Khezri

**Position**

Anesthesiologist/assistant professor

**Other areas of specialty/work**

**Street address**

Taleghani Street, Kosar Hospital

**City**

Qazvin

**Postal code**

3418899581

**Phone**

+98 28 3222 2452

**Fax**

**Email**

mkhezri@qums.ac.ir

**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*