

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

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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

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

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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