Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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.nSetting 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 salin 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
Thermometery 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 manonetery 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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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