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

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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

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
Thermometery 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 manonetery 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
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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
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Person responsible for updating data

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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