Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of the Effect of Diclofenac Suppositories and Intravenous Paracetamol in Postoperative Pain

Protocol summary

Summary

Back ground: the cesarean section is one of the most common surgical procedures that is more prevalent in Iran than Western societies. One of the complications of after cesarean section is the pain after surgery that , if not controlled properly, impairs communication between the mothers and their babies causing an unpleasant feeling. The acute pain control after cesarean is of great importance. Regarding the importance of pain control, there is an attempt in this research to compare the effects of two common non-narcotic medications to have a better control over acute pain after cesarean. Method: This study is a clinical trial. In this study, 88 patients with ASA class I and II at the age of 15-45 who underwent cesarean were selected. 100 mg diclofenac suppository for the first group and 1g of acetaminophen IV in 100 ml normal saline for the second group were repeated immediately after measurement and over 24 hours. The control of postpartum hemorrhage can be assessed by clinical examination, postoperative Hb 6-12 hours after surgery and Pad Score. Major outcome measures are postoperative pain and bleeding

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081829414N1**
Registration date: **2016-12-13, 1395/09/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-12-13, 1395/09/23

Registrant information

Name

Vahideh Rashtchi

Name of organization / entity

Zanjan university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Zanjan University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Diclofenac Suppositories and Intravenous Paracetamol in Postoperative Pain

Public title

the Effect of Diclofenac Suppositories on postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: ASA class I,II; age between 15-45 years old; candidate for emergent or elective cesarean section with spinal anesthesia. Exclusion criteria: when NSAIDS are contraindicated; morbid obesity; HTN; history of cardiovascular, respiratory, coronary artery, renal, gastrointestinal, neuromascular and liver diseases;

diabetes; coagulopathy; patients refusal; abnormal bleeding; infection in the site of spinal anesthesia.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Zanjan University of Medical Sciences

Street address
Zanjan University of Medical Sciences, Azadi blvd.

City
Zanjan

Postal code

Approval date
2015-02-06, 1393/11/17

Ethics committee reference number
ZUMS.REC.1393.197

Health conditions studied

1

Description of health condition studied
postoperative pain

ICD-10 code
XXI

ICD-10 code description
XXI Factors influencing health status and contact with health services

Primary outcomes

1

Description
Postoperative pain

Timepoint
6, 12, 18 and 24 hours after operation

Method of measurement
visual analogue scale

Secondary outcomes

1

Description
Postoperative bleeding

Timepoint
6 and 12 hours after operation

Method of measurement
Pad score

Intervention groups

1

Description
In one group 100 mg diclofenac suppository immediately after operation and repeat over 6 hours.

Category
Treatment - Drugs

2

Description
In the other group 1g of acetaminophen IV in 100 ml normal saline administered immediately and every 6 hours for 24 hours.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Musavi hospital

Full name of responsible person
Dr. Behnaz Molaei

Street address
Ayatollah Musavi hospital, Gavazang road

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Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Dr Alireza Shogli

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Zanjan University of Medical Sciences, Azadi blvd.
City
Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
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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