Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Ḍiclofenac rectal suppository in Pentazocin intake in pain after cesarean section in patients referred to Shahid Sadougi Hospital

Protocol summary

Summary

Introduction: Cesarean section in Iran is two times higher than the global statistics. Diclofenac rectal suppository as analgesic has not the opioid and gastro intestinal side effects. This study was performed to show Effect of Diclofenac rectal suppository on Pentazocin intake for releife pain after cesarean. Material and methods: This study was performed by RCT method. RCT was done on 80 women that undergo the cesarean section, by the same anesthesia method, and were selected randomly in two groups of 40 persons of diclofenac and Pentazocin. In diclofenac group imediately after cesarean section, rectal suppository Diclofenac 100mg, and in 12, 24 and 36 hours after surgery, the rectal suppository Diclofenac 50mg was used and is necessary for more relief pain was injected the Pentazocin Amp 30mg IM. Also in Pentazocin group for pain relief according to the routine method was injected the Pentazocin Amp 30mg IM. For both two groups, the number of Pentazocin was used and pain severity was measured by Visual Analog Scale (VAS) in 3,12 an 24 hours after surgery and discharge time, and then was determind the drugs side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206176826N3**
Registration date: **2012-07-13, 1391/04/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-07-13, 1391/04/23

Registrant information

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Mahshid Bokaie

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2010-02-19, 1388/11/30

Expected recruitment end date

2011-03-21, 1390/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ḍiclofenac rectal suppository in Pentazocin intake in pain after cesarean section in patients referred to Shahid Sadougi Hospital

Public title

Effect of Ḍiclofenac rectal suppository in Pentazocin intake in pain after cesarean section in patients referred to Shahid Sadougi Hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 18-35 years old pregnant women; second or third time of cesarean section; single fetus and gestational age 37-42 week. Exclusion criterion: every

complication during Anastasia and operation

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study was carried out by randomized controlled trial (RCT) method on 80 qualified cesarean women under identical anesthetic conditions; the statistical population was randomly divided into two 40-persons groups, i.e. Diclofenac and Pentazocine. In Diclofenac group, the first Diclofenac rectal suppository was deployed immediately after cesarean and next suppositories were inserted 12, 24 and 36 hours following the operation; 30mg muscular Pentazocine ampoule was injected as sedative where necessary. In Pentazocine group, only 30 mg muscular Pentazocine was injected for pain sedation as routine. For two groups, number of administered Pentazocine, pain intensity in 12, 24 and 36 hours after operation and discharge time were measured by means of visual-analogue scale (VAS) of pain evaluation, and, side effects of medicines were determined as well.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Sadougi University of Medical Sciences

Street address
Bahonar squ- Yazd

City
Yazd

Postal code

Approval date
2010-01-14, 1388/10/24

Ethics committee reference number
92097

Health conditions studied

1

Description of health condition studied
Post cesarean pain

ICD-10 code
R10.2

ICD-10 code description
Pelvic and perineal pain

Primary outcomes

1

Description
Pain severity

Timepoint
12, 24 and 36 hours and discharge time.

Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Numder of amp pentasocine (30 mg) used

Timepoint
Till discharge time

Method of measurement
Number of amp

Intervention groups

1

Description
Diclofenac Na rectal supp 50 , 100mg Aborayhan factory after cesarean section frist dose of Diclofenac Na rectal supp100mg and then 12,24, 36 hour after surgery Diclofenac Na rectal supp50mg was done

Category
Treatment - Drugs

2

Description
Pentazosin Amp (30mg) if necessary Tplidaro Factory

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi hospital

Full name of responsible person

Street address

City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadougi University of Medical Sciences
Full name of responsible person
Fatemeh Ezeddini Ardakani
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Bahonar squ- Yazd
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadougi 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

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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