

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative effect of intravenous acetaminophen and suppository of diclofenac on pain relief after elective cesarean section under spinal anesthesia.

Protocol summary

Summary

The aim of this study is comparison of intravenous acetaminophen with diclofenac suppository on postoperative pain in parturients scheduled for elective cesarean section under spinal anesthesia. This is randomized double blind clinical trial containing placebo (phase 2-3) in 84 parturients with ASA class 1&2 candidate for cesarean section under spinal anesthesia. Patients with liver, renal, cardiac disease, hypertension, diabetes, allergic reaction, emergency cesarean, bleeding disorders & spinal anesthesia contraindications is excluded. After spinal anesthesia by 25 G needle and injection of 12.5 mg bupivacaine 0.5% in subarachnoid space cesarean is done. After skin closure in A group 1gr IV acetaminophen in 100ml N/S within 30 minutes association to placebo suppository and in D group 100ml intravenous N/S with diclofenac suppository is administered and the same drug in obstetric ward. Systolic & diastolic blood pressure; heart rate; blood oxygenation and VAS of pain in preadministration, arrive to recovery, 15 minutes after stay in recovery, exit of recovery and 2, 4, 6, 12, 18 and 24 hours after surgery, analgesic requirement, nausea and vomiting and patient satisfaction is recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013010710841N3**
Registration date: **2013-04-12, 1392/01/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-04-12, 1392/01/23

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1827 7012

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Recruitment status

Recruitment complete

Funding source

Hamadan University Of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-06-21, 1392/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of intravenous acetaminophen and suppository of diclofenac on pain relief after elective cesarean section under spinal anesthesia.

Public title

Evaluation of intravenous acetaminophen & Diclofenac Suppository on postoperative pain reduction in cesarean section.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Parturients with ASA class 1&2; 18-45 years; candidate for elective cesarean section under spinal anesthesia. Exclusion criteria: Liver disease; Renal disease; Cardiac disease; Hypertension; Peptic ulcer; Pre-eclampsia&Eclamsia; Diabetes; Allergic reaction; Emergency cesarean section; Bleeding disorder or Anticuaagolant drug History; Increasing ICP; Local skin infection; Neurologic disorders.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **84**

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

Hamadan University Of Medical Sciences

Street address

Hamadan University Of Medical Sciences/Medical School, Fahmide Street

City

Hamadan

Postal code

65178

Approval date

2012-11-13, 1391/08/23

Ethics committee reference number

2962/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied

cesarean postoperative pain

ICD-10 code

089.9

ICD-10 code description

Complication of anaesthesia during the puerperium, unspecified

Primary outcomes

1

Description

Pain score

Timepoint

Before drug administration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6, 12, 18 & 24 hours after surgery.

Method of measurement

10 centimeter ruler

2

Description

Systolic Blood Pressure

Timepoint

Before drug administration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6, 12, 18 & 24 hours after surgery.

Method of measurement

Non invasive Blood Pressure Monitoring

3

Description

Diastolic Blood Pressure

Timepoint

Before drug administration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6, 12, 18 & 24 hours after surgery.

Method of measurement

Non invasive Blood Pressure Monitoring

4

Description

Heart rate

Timepoint

Before drug administration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6, 12, 18 & 24 hours after surgery.

Method of measurement

Pulse oximetry

5

Description

Blood oxygenation

Timepoint

Before drug administration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6, 12, 18 & 24 hours after surgery.

Method of measurement

Pulse oximetry

6

Description

Analgesic requirement in 24 hours

Timepoint

During 24 hours

Method of measurement

Questionnaire

7

Description

Patients satisfaction

Timepoint

During 24 hours

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Nausea

Timepoint

during 24 hours

Method of measurement

Observation

2

Description

Vomiting

Timepoint

during 24 hours

Method of measurement

Observation

3

Description

Epigastric Pain

Timepoint

During 24 hours

Method of measurement

Observation

Intervention groups

1

Description

After skin closure in Acetaminophen group 1gr IV acetaminophen in 100ml N/S within 30 minutes association to placebo suppository is administered and the same in obstetric ward by nursing in QID.

Category

Treatment - Drugs

2

Description

After skin closure in Diclophenac group 100ml IV N/S

within 30 minutes association to Diclophenac suppository is administered and the same in obstetric ward by nursing in QID.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemy Hospital

Full name of responsible person

Nahid Manouchehrian

Street address

Fatemy Hospital, Pasdaran Street

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University Of Medical Science ,Vice chancellor for research

Full name of responsible person

Dr. Heidar Tavilany

Street address

Hamadan University Of Medical Sciences, Medical School, Fahmide Street

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamadan University Of Medical Science ,Vice chancellor for research

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

Hamadan University of Medical Science

Full name of responsible person

Nahid Manouchehrian

Position

Assistant Professor Of Hamadan University of Medical Science

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Special Board Of Anesthesia

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Web page address**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