Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Summary

The aim of this study is comparsion of intravenous acetaminophen with diclophenac suppository on postoperative pain in parturients sheduled for elective cesarean section under spinal anesthesia . This is randomized double blind clinical trial contianing placebo(phase 2-3)in 84 parturients with ASAclass1&2 candidate for cesareaction 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 suppositoryand in D group 100ml intravenous N/S with diclophenac suppository is adminstrated and the same drug in obstetric ward.systolic & diastolic blood pressure;heart rate; blood oxygenation and VAS of pain in preadminstration,arrive to recovery,15 minutes after stay in recovery,exit of recovery and 2,4,6,12,18 and 24 hours after sergury,analgesic requirment,neusea and vomiting and patient satisfactionl 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

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Nahid Manuchehrian
Name of organization / entity
Hamedan University of Medical Sciences
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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 diclophenac on pain relief after elective cesarean section under spinal anesthesia.

Public title

Evaluation of intravenous acetaminophen & Diclophenac 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 Anticuagolant 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 adminstration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6,1 2, 18 & 24 hours after sergury.

Method of measurement
10 centimeter ruller

2

Description
Systolic Blood Pressure

Timepoint
Before drug adminstration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6,1 2, 18 & 24 hours after sergury.

Method of measurement
Non invasive Blood Pressure Monitoring

3

Description
Diastolic Blood Pressure

Timepoint
Before drug adminstration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6,1 2, 18 & 24 hours after sergury.

Method of measurement
Non invasive Blood Pressure Monitoring

4

Description
Heart rate

Timepoint
Before drug adminstration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6,1 2, 18 & 24 hours after sergury.

Method of measurement
Pulse oximetry

5

Description
Blood oxygenation

Timepoint
Before drug adminstration; arrive to recovery; 15 minutes after stay in recovery; exit from recovery; 2, 4, 6,1 2, 18 & 24 hours after sergury.

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 adminstrated 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 adminstrated 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

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Assistant Professor Of Hamadan University of Medical Science
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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