Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the analgesic effect of bupivacaine, bupivacaine with adrenaline and bupivacaine with Epsom on the pain after cesarean section

Protocol summary

Summary

Objective: Comparing the analgesic effect of bupivacaine, bupivacaine with adrenaline and bupivacaine with Epsom on the severity of pain after cesarean section in patients hospitalized in Rouhani Hospital of Babol University of Medical Science, 2015. Study design and population: Randomized single blind in 160 patients divided in to 4 groups. Inclusion criteria: Term and single pregnancy; ASA class I or II; Height: 180 to 170 centimeter; End pregnancy weight from 70 to 100 kilogram and undergoing elective cesarean section. Exclusion criteria: having hypersensitivity to amide local anesthetics; history of opioid drugs and calcium channel blockers; a tonic uterus after surgery or prolong surgical time more than 1.5 hours. Interventions: in first group: 50 milliliter normal saline is injected intravenously during 15 minutes .Then 10 milliliter of 0.5%bupivacaine injected subcutaneously in 10 separate injections after repairing fascia. Group (2): After injecting 50 milliliter normal saline, 0.1 milliliter of adrenaline 1:1000 with 10 milliliter of 0.5% bupivacaine injected subcutaneously after repairing fascia. Group (3): 50 milligrams per kilogram of magnesium sulfate 50% injected intravenously over 15 minutes and then 10 milliliter 0.5% bupivacaine that diluted with 20 milliliter of normal saline injected subcutaneously after repairing fascia. Control group: 50 milliliter normal saline injected intravenously over 15 minutes, and 20 milliliter normal saline injected subcutaneously. Severity of pain will evaluate by visual Analogous Scale (VAS) and hemodynamic indices (heart rate and blood pressure(in 2, 6, 12, 18 and 24 hours after surgery . Primary outcomes: severity of pain

General information

Acronym

ICP: Intra Cranial Pressure

IRCT registration information

IRCT registration number: **IRCT2015090723926N1**
Registration date: **2016-02-18, 1394/11/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-18, 1394/11/29

Registrant information

Name

Rabeeh Rouhani

Name of organization / entity

Babol university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8256

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Babol University of Medical Science

Expected recruitment start date

2015-07-29, 1394/05/07

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the analgesic effect of bupivacaine, bupivacaine with adrenaline and bupivacaine with Epsom on the pain after cesarean section

Public title
Comparison of the effects of local anesthetics on the severity of pain after cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Term Pregnancy; single pregnancy; ASA class I or II; Height 180 to 170 cm,; End pregnancy weight from 100 to 70 kg and undergoing elective cesarean section. Exclusion criteria: having hypersensitivity to amide local anesthetics (eg, bupivacaine and lidocaine), magnesium sulfate and epinephrine; history of opioid drugs; coagulopathy; seizure; cardiovascular disease; mental disorders; asthma and chronic obstructive pulmonary disease; high ICP; kidney disease; liver disease; atrioventricular block; history of calcium channel blockers; A tonic uterus after surgery or prolong surgical time more than 1.5 hours

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The patient is unaware of the method of sedation so this study is single blind and samples based on Table of random numbers will selected randomizely

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Commitee of Babol University of Medical Science

Street address
Rouhani hospital, Ganjafrouz street, Babol, Mazandaran

City
Babol

Postal code
47176-47745

Approval date
2015-07-28, 1394/05/06

Ethics committee reference number
mubabol.rec.1394.101

Health conditions studied

1

Description of health condition studied
Anesthesia and delivery

ICD-10 code
XV

ICD-10 code description
Complications of anaesthesia during labour and delivery

Primary outcomes

1

Description
severity of pain

Timepoint
2, 6, 12, 18 and 24 hours after after starting the intervention

Method of measurement
visual Analogous Scale of pain

Secondary outcomes

1

Description
Blood pressure

Timepoint
2, 6, 12, 18 and 24 hours after starting intervention

Method of measurement
Observation and record

2

Description
Heart rate

Timepoint
2, 6, 12, 18 and 24 hours after starting intervention

Method of measurement
Observation and record

Intervention groups

1

Description
Intervention Group(1): 50 milliliter normal saline is injected intravenously during 15 minutes at the beginning of surgery .then 10 milliliter of 0.5%bupivacaine which is diluted with 10 milliliter of

normal saline to total of 20 milliliter injected subcutaneously in 10 separate injections of 2 milliliter in volume after repairing fascia

Category

Treatment - Drugs

2

Description

Intervention group (2): At the beginning of surgery 50 milliliter normal saline intravenously injected. Then 0.1 milliliter of adrenaline 1:1000 + 10 milliliter of 0.5% bupivacaine is diluted with normal saline to total of 20 milliliter injected subcutaneously after repairing fascia

Category

Treatment - Drugs

3

Description

Intervention group (3): 50 milligrams per kilogram of magnesium sulfate 50% by volume of 50 milliliter normal saline can be injected intravenously over 15 minutes And 10 milliliter 0.5% bupivacaine with 20 milliliter of normal saline injected subcutaneously after repairing fascia

Category

Treatment - Drugs

4

Description

Control group: 50 milliliter normal saline injected intravenously over 15 minutes, and 20 milliliter normal saline injected in subcutaneous fat after repairing fascia

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Operation Room of Rouhani Hospital

Full name of responsible person

Rabeeh Rouhani

Street address

Rouhani Hospital, Ganjafroz Street, Babol

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Babol University of Medical Sciences

Full name of responsible person

Mohsen Rezazadeh

Street address

Babol university of medical science, Gangafroz Street, Babol

City

Babol

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, Babol 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

Babol university of medical science

Full name of responsible person

Rabeeh Rouhani

Position

Student of Master Degree

Other areas of specialty/work

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Person responsible for scientific inquiries

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Zinatossadat Bozari

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Person responsible for updating data

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Student of Master Degree
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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