Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Bupivacaine 0.5% , Lidocaine 5% , Pethidine , Lidocaine 5% & intratecal on the incidence of decrease blood pressure , nausea and vometing for elective caesarean section

Protocol summary

Study aim

To compare the effect of Bupivacaine 0.5% and Lidocaine 5% - Pethedine and Lidocaine 5% intrathecal on the incidence of hypotension and nausea and vomiting during cesarean section

Design

Randomised single blind clinical trial, parallel groups trial. Randomisation was centralised and computerised

Settings and conduct

Methods: Patients will be divided into three groups of 25 people and spinal anesthesia will be performed for them. Local anesthetic in group one is: Lidocaine 5% - Pethedine (60 mg Lidocaine 5% -15 mg Pethedine), in group 2: 75 mg Lidocaine 5% and in group three: 15 Bupivacaine 0.5 % . Place of study:Gerash Amir-al-Momenin medical and educational center

Participants/Inclusion and exclusion criteria

Study population: 75 women undergoing cesarean section. Inclusion criteria: term pregnancy (42-37 weeks); willingness to participate in the study; NPO; ASA I; elective caesarean section. Exclusion criteria: operation duration more than 80 minutes; using beta tocolytic, fetal abnormalities ; pregnancy complications ; failure in performing spinal; low level of blocks; stomachache; metabolic diseases, hypertension; nausea and vomiting before surgery; any underlying diseases; complications during surgery; arterial or venous disease in lower extremities; defects in the immune system and gestational diabetes, smoking, alcoholism and opium addiction, malnutrition; anemia.

Intervention groups

group one : Lidocaine 5% - Pethedine (60 mg Lidocaine 5% -15 mg Pethedine) intratecal group 2 : 75 mg Lidocaine 5% intratecal group 3 : 15 Bupivacaine 0.5 % intratecal

Main outcome variables

pulse rate, mean, systolic and diastolic blood pressure will be measured and recorded immediately after the block every 3 minutes and then every 15 minutes until the end of the recovery. The incidence of itching, nausea and vomiting during surgery and recovery will be measured and recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170417033491N2**
Registration date: **2018-08-09, 1397/05/18**
Registration timing: **retrospective**

Last update: **2018-08-09, 1397/05/18**
Update count: **0**

Registration date

2018-08-09, 1397/05/18

Registrant information

Name
Jalal Saem
Name of organization / entity
Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 713634001
Email address
saemj@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vic Chancellor for Research, Gerash University of Medical Sciences

Expected recruitment start date

2017-10-04, 1396/07/12

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Bupivacaine 0.5% , Lidocaine 5% , Pethidine , Lidocaine 5% & intratecal on the incidence of decrease blood pressure , nausea and vometing for elective caesarean section

Public title

Study the effect of Bupivacaine 0.5% , Lidocaine 5%, Pethidine , Lidocaine 5% & intratecal on the incidence of decrease blood pressure, nausea and vomiting for elective caesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 45 - 18 years Term pregnancy (42-37 weeks) Willingness to participate in the study NPO (Nil Per Os) ASA I Elective caesarean section

Exclusion criteria:

Operation duration more than 80 minutes Using ritodrine or other beta tocolytic Fetal abnormalities or pregnancy complications Failure in performing spinal Low level of blocks (block level lower than T8) Stomachache; metabolic diseases; hypertension; nausea and vomiting before surgery Any underlying diseases Complications during surgery Arterial or venous disease in lower extremities Defects in the immune system and gestational diabetes Smoking Alcoholism and opium addiction Malnutrition Anemi

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple allocation by Statistical software

Blinding (investigator's opinion)

Single blinded

Blinding description

The patients will be blind to the kind of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gerash University of Medical Sciences

Street address

Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran

City

Gerash

Province

Fars

Postal code

58666 – 74417

Approval date

2017-10-02, 1396/07/10

Ethics committee reference number

IR.GERUMS.REC.1396.1032

Health conditions studied

1

Description of health condition studied

Caesarean Section

ICD-10 code

O.82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Percentage of people who have nausea and vomiting during surgery

Timepoint

During surgery and then until the end of the recovery

Method of measurement

Observasion

2

Description

Blood Pressure

Timepoint

Measure and record pulse rate, mean, systolic and diastolic blood pressure immediately after the block (during surgery) every 3 to 15 minutes and then every 5 minutes until the end of the recovery

Method of measurement

Automatic sphygmomanometer

Secondary outcomes

1

Description
Itching
Timepoint
Every 3 to 15 minutes and then every 5 minutes until the end of the recovery
Method of measurement
Observasion

Intervention groups

1

Description
Patients in group one received lidocaine 5% - pethedine (60 mg lidocaine 5% -15 mg pethedine as local anesthetic.
Category
Treatment - Drugs

2

Description
Patients in group two received 75 mg lidocaine 5% as local anesthetic.
Category
Treatment - Drugs

3

Description
Patients in group three received 15 bupivacaine 0.5 % as local anesthetic.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin hospital
Full name of responsible person
Jalal Saem
Street address
Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran
City
Gerash
Province
Fars
Postal code
58666 – 74417
Phone
+98 71 5244 2002
Email
saemj@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gerash University of Medical Sciences
Full name of responsible person
Dr Mehdi Mohsenzadeh
Street address
Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran
City
Gerash
Province
Fars
Postal code
۵۸۶۶۶ – ۷۴۴۱۷
Phone
+98 71 5245 2339
Email
saemj@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gerash University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Gerash University of Medical Sciences
Full name of responsible person
Jalal Saem
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran
City
Gerash
Province
Fars
Postal code

58666 – 74417
Phone
+98 71 5244 8108
Fax
Email
saemj@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gerash University of Medical Sciences
Full name of responsible person
Jalal Saem
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran
City
Gerash
Province
Fars
Postal code
58666 – 74417
Phone
+98 71 5244 8108
Fax
Email
saemj@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Gerash University of Medical Sciences
Full name of responsible person
Jalal Saem
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Gerash University of Medical sciences, Student Blv, Imam Hussain (AS) Blv, Gerash, Fars Province, Iran
City
Gerash
Province
Fars
Postal code
58666 – 74417
Phone
+98 71 5244 8108
Fax
Email
saemj@sums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data will be coded without the names of the participants.
When the data will become available and for how long
Start the access period 6 months after publishing the results
To whom data/document is available
The published article for this study will be accessible to everyone, but other information will only be available to the sponsoring organization.
Under which criteria data/document could be used
The published paper for this study will be accessible to everyone, but other information will only be available to the sponsoring organization
From where data/document is obtainable
Visit the Research Deputy of the Gerash University of Medical Sciences.
What processes are involved for a request to access data/document
Visit the Research Deputy of the University of Medical Sciences. The vice chancellor will refer the applicant to the researcher if the applicant agrees.
Comments