

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of 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

Protocol summary

Study aim

To compare the effect of Bupivacaine 0.5% and Lidocaine 5% - Pethidine 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% - Pethidine (60 mg Lidocaine 5% -15 mg Pethidine), 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% - Pethidine (60 mg Lidocaine 5% -15 mg Pethidine) 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 vomiting 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

Observation

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

Observation

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

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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

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Anesthesiology

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Gerash University of Medical sciences, Student Blv,

Imam Hussain (AS) Blv, Gerash, Fars Province, Iran

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Province

Fars

Postal code

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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