

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparing the Analgesic Effects of Lidocaine Plus Buprenorphine and Lidocaine Alone In Women With Cesarean Section Under Spinal Anesthesia, Babol University of Medical Sciences

Protocol summary

Summary

Aims: Evaluating the effect of Buprenorphine Lidocaine in comparison to Lidocaine alone in patients candidate for cesarean section to decrease the post-operation pain
Key criteria of inclusion and exclusion: Maternal or Fetal Contraindication for Spinal Anesthesia; Severe Fetus Distress; Emergency Cesarean; Addiction, Drug or OTC Abuse, Using Anti-epileptic Drugs, Blood Pressure More Than 140/90 mmHg, Gestational Diabetes, Psychiatric Problems; Uncontrolled Co-existent Internal Disease
Study population: All patients candidate for elective cesarean section in ASA class I aged 17-41 years
Sample size: 400
The intended intervention, time and primary outcome: Population randomly will divide into two groups: case group (Lidocaine and Buprenorphine) and control group (Lidocaine). They will be followed up to one week regards to the complications and effects after blind induction of intrathecal anesthesia by assistant of anesthesiology. a same standard technique for spinal anesthesia induction. patient will be followed in ward or after discharge for about 1 week. Data will be coded and entered into computer by appropriate software and will analyze.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022112552N1**
Registration date: **2013-06-07, 1392/03/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-07, 1392/03/17

Registrant information

Name

Ali Jabbari

Name of organization / entity

Babol University of Medical Sciences, Golestan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 11 1223 8296

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Recruitment status

Recruitment complete

Funding source

Self Sponsored and Small Grant of Babol University of Medical Sciences. Some of The Drug and Equipment Will Be Provided By Hospitals Dependent on Babo University of Medical Sciences.

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-09-06, 1392/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the Analgesic Effects of Lidocaine Plus Buprenorphine and Lidocaine Alone In Women With Cesarean Section Under Spinal Anesthesia, Babol University of Medical Sciences

Public title

Benefits of Using Intrathecal Buprenorphine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: All pregnant women candidate for elective cesarean section, in ASA class I (American Society of Anesthesiology) aged 17-41 Years. Exclusion Criteria: Maternal or fetal contraindication for spinal anesthesia; Severe fetus distress; Emergency Cesarean; Addiction, Drug or OTC abuse, Using Anti-epileptic drugs, Blood pressure more than 140/90 mmHg, Gestational diabetes, Psychiatric problems; Uncontrolled co-existent internal disease

Age

From **17 years** old to **41 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **400**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine, Babol University of Medical Sciences

Street address

University Sq

City

Babol

Postal code

Approval date

2009-04-22, 1388/02/02

Ethics committee reference number

1115

2

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Babol University of Medical Sciences

City

Babol

Postal code

Approval date

2013-03-09, 1391/12/19

Ethics committee reference number

2159

Health conditions studied

1

Description of health condition studied

Post operative pain management and adverse effect of intrathecal buprenorphine

ICD-10 code

P04.0

ICD-10 code description

Reactions and Intoxications From Maternal Opiates and Tranquillizers Administered During Labour and Delivery

Primary outcomes

1

Description

Pain free period after operation

Timepoint

Pain assessment before, during and after surgery with Visual Analogue Score (VAS)

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Post Operative Nausea

Timepoint

Before anesthesia, 5 Min interval after spinal anesthesia, then every 6 hours in the ward

Method of measurement

Questionnaire

2

Description

Post Operative Vomiting

Timepoint

Before anesthesia, 5 Min interval after spinal anesthesia, then every 6 hours in the ward

Method of measurement

Questionnaire

3

Description

Hemodynamic Factors

Timepoint

Before anesthesia, 5 Min interval after spinal anesthesia,

then every 6 hours in the ward
Method of measurement
Standard Manometer, Standard Therometer

Intervention groups

1
Description
In the Case group, 65-70 mg (1.3 to 1.4 cc) of 5% Lidocaine Plus 0.2 cc of Bupernorphine Will be Infused. And in the Control Group, 65-70 mg (1.3-1.4 cc) of 5% Lidocaine Plus 0.2 cc of 0.9% Saline Normal Will Be Infused.
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Ayatollah Rohani Hospital
Full name of responsible person
Ali Jabbari
Street address
Department of Anesthesiology and Critical Care Medicine, Ayatollah Rohani Hospital
City
Babol

2
Recruitment center
Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
Ebrahim Alijanpour
Street address
Department of Anesthesiology, Shahid Beheshti Hospital
City
Babol

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Babol Univesity of Medical Sciences
Full name of responsible person
Dr.Alijanpour
Street address
Babol Univesity of Medical Sciences
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes
Title of funding source
Babol Univesity of Medical Sciences
Proportion provided by this source
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

2
Sponsor
Name of organization / entity
Babol Univesity of Medical Sciences
Full name of responsible person
Ebrahim Alijanpour (Self Sponsored)
Street address
Department of Anesthesiology and Critical Care Medicine, Ayatollah Rohani Hospital
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol Univesity of Medical Sciences
Proportion provided by this source
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 Univesity of Medical sciences, Golestan Univesity of Medical Sciences
Full name of responsible person
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Position
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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