

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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)

##### Phone

+98 11 1223 8296

##### Email address

anesth.jabbari@mubabol.ac.ir

#### 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**

Ali Jabbari

**Position**

MD, MPH

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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**City**

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amir\_a\_78@yahoo.com

**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*