

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The effect of intra abdominal infiltration with bupivacaine in reducing postoperative diclofenac need in elective cesarean sections.

#### Protocol summary

##### Summary

The aim of this study is to determine the effect of intra abdominal wall infiltration with bupivacaine to reduce post operative diclofenac need in elective cesarean sections. Inclusion criteria were: women with first single term pregnancy who are candidate for elective caesarean section, spinal anaesthesia, BMI between 20 to 25 before pregnancy, and time of surgery less than 40 minutes. Exclusion criteria were: bleeding, atonia or any unpredicted accident during or after surgery. fannenstiel incision, opium consumption, underlying disease, history of previous abdominal surgery, sensitivity to amid drugs. In this double- blind, placebo-controlled trial, 60 healthy women with single term pregnancy, after obtaining written informed consent, were randomized into two groups. Patients underwent spinal anesthesia, and then they received a combination of 30cc of 0.25% bupivacaine with 1.5cc of 1:200000 epinephrine as intra abdominal wall infiltration or equal volume of saline in cesarean section at the time of abdominal closure. Pain was assessed using a visual analogue scale 1, 2, 3, 4, 8 and 12 h after the operation. Also mean diclofenac consumption was assessed during 12 h after the operation. The final analysis was done with statistical tests including Chi Square, Non Parametric test and Mann-withny U by SPSS ( $P < 0.05$  was considered significant). Mean pain scores after the operation and mean diclofenac consumption in 12 h were compred between two groups. Also the time we prescribed diclofenac was compared between two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138812243574N1**

Registration date: **2010-05-29, 1389/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-05-29, 1389/03/08

##### Registrant information

###### Name

Nader Esmalipour

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 1322 5624

###### Email address

esmailpour@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Research vice chancellorship -Guilan university of medical sciences

##### Expected recruitment start date

2008-12-28, 1387/10/08

##### Expected recruitment end date

2009-09-17, 1388/06/26

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of intra abdominal infiltration with bupivacaine in reducing postoperative diclofenac need in elective cesarean sections.

##### Public title

The effect of intra abdominal infiltration with bupivacaine in reducing postoperative diclofenac need in elective

cesarean sections.

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria were: women with first single term pregnancy who are candidate for elective caesarean section, spinal anaesthesia, BMI between 20 to 25 before pregnancy, and time of surgery less than 40 minutes.

Exclusion criteria were: bleeding, atonia or any unpredicted accident during or after surgery. fannenstiel incision, opium consumption, underlying disease, history of previous abdominal surgery, sensitivity to amid drugs

### **Age**

From **16 years** old to **39 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Research vice chancellorship-Guilan university of medical sciences

##### **Street address**

Namjo st., Research vice chancellorship, Guilan university of medical sciences

##### **City**

Rasht

##### **Postal code**

#### **Approval date**

2009-10-11, 1388/07/19

#### **Ethics committee reference number**

4186

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Delivery by elective caesarean section

#### **ICD-10 code**

O82.0

#### **ICD-10 code description**

Delivery by elective caesarean section

## **Primary outcomes**

### 1

#### **Description**

Pain Severity

#### **Timepoint**

1, 2, 3, 4, 8, and 12 hours after operation

#### **Method of measurement**

Visual analogue scale

## **Secondary outcomes**

### 1

#### **Description**

Duration of painless period

#### **Timepoint**

1, 2, 3, 4, 8, and 12 hours after operation

#### **Method of measurement**

The time span between the end of the operation and the time we prescribed first dose of diclofenac

### 2

#### **Description**

Diclofenac use after operation

#### **Timepoint**

Over 12 hours

#### **Method of measurement**

Total diclofenac consumption

## **Intervention groups**

### 1

#### **Description**

intra abdominal wall infiltration of 30 cc of 0.25% bupivacaine

#### **Category**

Treatment - Drugs

### 2

#### **Description**

intra abdominal wall infiltration of 30 cc normal saline

#### **Category**

Placebo

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Guilan university of medical sciences, Alzahra Hospital

**Full name of responsible person****Street address****City**

Rasht

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Research vice chancellorship, Guilan university of medical sciences

**Full name of responsible person**

Dr Abdolrasol Sobhani

**Street address**

Namjo st., Research vice chancellorship, Guilan university of medical sciences

**City**

Rasht

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research vice chancellorship, Guilan 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**

Guilan university of medical sciences

**Full name of responsible person**

Dr Nader Esmailpour

**Position**

Assistant Professor of Obstetric and Gynecology, Guilan university of Medical Sciences

**Other areas of specialty/work****Street address**

Reproductive Health Research center, Department of Ob &Gyn, Alzahra Hospital, Guilan university of Medical Sciences , Namjo st., Rasht

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

Dr Nader Esmailpour

**Position**

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**Other areas of specialty/work****Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Reproductive Health Research center

**Full name of responsible person**

Seyede Fatemeh Dalil Hirati

**Position**

Bs in Midwifery

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**Postal code****Phone****Fax****Email****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*