

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison the effect of preincisional local infiltration of Lidocaine 2% and Marcaine 0/25% on severity of pain in patients after ceasarian section in ALZAHRA hospital in Rasht on 2011

#### Protocol summary

##### Summary

The purpose of this study is to compare the effect of preincisional local infiltration of lidocaine 2% and marcaine 0/25% on severity of pain in patients after ceasarian section in Alzahra hospital in rasht . After signing the informed consent , this double blind study, will be perfomed on 87 primiparum women with no history of drug reactions to anesthetics. The patients will randomly divided to 3 intervention groups with marcaine, lidocaine and control group , who will receive normal saline. If surgery prolonged more than 1 hour, or another surgery needed, the case will be excluded. The severity of pain in 1, 2, 3, 4, 8 and 12 hours after surgery will be assessed by visual analog scale, total dose of analgesic used and mean pain scale in the patient will be compare in study groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201102131946N6**

Registration date: **2011-05-09, 1390/02/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-05-09, 1390/02/19

##### Registrant information

##### Name

Mandana Mansur Ghanaie

##### Name of organization / entity

Giulan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1322 5624

##### Email address

m\_m\_ghanaie@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research, Guilan University of Medical Sciences

##### Expected recruitment start date

2011-03-21, 1390/01/01

##### Expected recruitment end date

2011-08-23, 1390/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of preincisional local infiltration of Lidocaine 2% and Marcaine 0/25% on severity of pain in patients after ceasarian section in ALZAHRA hospital in Rasht on 2011

##### Public title

Comparison the effect of preincisional local infiltration of Lidocaine 2% and Marcaine 0/25% on severity of pain in patients after Ceasarian section.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Primiparity , Indications for spinal anesthesia . Exclusion criteria: Surgery duration last more than 1 hour, need to another surgery , history of drug reaction to anesthetics, contraindications for spinal anesthesia .

## Age

From **15 years** old to **45 years** old

## Gender

Female

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **87**

## 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

Ethics Committee of Guilan Medical Science  
University

##### Street address

Melat st, Namjoo Ave

##### City

Rasht

##### Postal code

#### Approval date

2011-03-04, 1389/12/13

#### Ethics committee reference number

35

## Health conditions studied

### 1

#### Description of health condition studied

Pregnancy, childbirth and the puerperium

#### ICD-10 code

O74.8

#### ICD-10 code description

Other complications of anaesthesia during labour and delivery

## Primary outcomes

### 1

#### Description

Pain after cesarian section.

#### Timepoint

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

#### Method of measurement

Visual Analog Pain Scale (VAS)

## Secondary outcomes

### 1

#### Description

The mean score of pain after surgery

#### Timepoint

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

#### Method of measurement

Visual Analog Pain Scale (VAS)

### 2

#### Description

The dose of analgesic used.

#### Timepoint

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

#### Method of measurement

mg

### 3

#### Description

Time of the first dose of analgesics administration.

#### Timepoint

After surgery finished until the first dose of analgesics

#### Method of measurement

Hours

### 4

#### Description

Patients mobilization time

#### Timepoint

After surgery finished until the Patients mobilization time

#### Method of measurement

Hours

## Intervention groups

### 1

#### Description

Single dose of 0.5 mg/kg of marcaine0.25% with 30cc volume will infiltrated in peritoneum, facia and muscle

#### Category

Treatment - Drugs

### 2

#### Description

Single dose of 4 mg/kg of lidocaine2% with 30cc volume will infiltrated in peritoneum, facia and muscle

#### Category

Treatment - Drugs

### 3

#### Description

Single dose of Normal saline with 30cc volume will infiltrated in peritoneum, facia and muscle

#### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Alzahra hospital-Guilan University of Medical Sciences

###### Full name of responsible person

###### Street address

Alzahra hospital-Namjo street

###### City

Rasht

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Vice Chancellor for research, Guilan University of Medical Sciences

###### Full name of responsible person

Dr. Abdolrasol Sobhani

###### Street address

Mellat St., Namjoo Ave.

###### City

Rasht

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Vice Chancellor for research, 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. Mandana Mansour Ghanaie

#### Position

Obstetrics & Gynecologist

#### Other areas of specialty/work

#### Street address

Reproduction Health research center, Alzahra hospital, Namjo street

#### City

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#### Postal code

#### Phone

+98 13 1322 5624

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m\_m\_ghanaie@yahoo.com

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### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Guilan University of Medical Sciences

##### Full name of responsible person

Dr. Mandana Mansour Ghanaie

##### Position

Obstetrics & Gynecologist

##### 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

Seyedeh Maryam Mousavi Chahardeh

##### Position

B.S

##### Other areas of specialty/work

##### Street address

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h\_fertility@gums.ac.ir

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*