

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

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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

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Person responsible for updating data

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Reproductive Health Research Center

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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