

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Clinical trial of Comparison of low-dose Midazolam and Propofol on nausea and vomiting induced during operation, in pregnant women undergoing cesarean section with spinal anesthesia

Protocol summary

Summary

After getting permission from ethics and research Committee of Jahrom university of Medical Sciences, this double blind clinical trial was performed on 42 patients having the inclusion criteria (Pregnant women aged 15 to 60 years old, Class 1 and 2 ASA, Cesarean section candidate, and No physical or mental illness). Patients were divided into two groups A and B randomly by Random Allocation software. They did not receive any special medicine before entering operation room. Before starting surgery, patients received 7 ml/kg Ringer serum and then while patients received 65 mg Lidocain 5% for spinal anesthesia, group A were under treatment with 1.5mg Midazolam and group B with 2cc (20mg) Propofol. At the end of surgery patients were transferred to the recovery room. They were kept in recovery room for at least 1 hour. Nausea and vomiting of patients were measured based on their feelings in 1, 3, 5, 10, 15, 30 and 60 minutes after spinal anesthesia by a self-instructive questionnaire. The patients and the investigator did not have any information about the drugs used. The aim of this study is to find the best medication to decrease nausea and vomiting after elective cesarean section.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031717039N1**
Registration date: **2014-07-30, 1393/05/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-30, 1393/05/08

Registrant information

Name

Marjan Jaladat

Name of organization / entity

Medical University of Jahrom

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Jahrom university of Medical Science

Expected recruitment start date

2013-06-22, 1392/04/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Comparison of low-dose Midazolam and Propofol on nausea and vomiting induced during operation, in pregnant women undergoing cesarean section with spinal anesthesia

Public title

Comparison of Midazolam and Propofol on nausea and vomiting induced during cesarean section with spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria
 Inclusion Criteria: Written formal consent for operation, Pregnant women aged 15 to 60 years old, Class 1 and 2 ASA, Cesarean section candidate, No physical or mental illness, No consumption of Sedative, Antidepressant, Sleeping or Psychotropic medicine. Exclusion Criteria: Weight more than 100 kg, Age more than 60 or less than 15, Drug or alcoholic abusers, Treatment by Anti depressant, sleeping and psychotropic pills, Inadequate cooperation with investigator to assess nausea and vomiting after operation, Hospitalization in ICU after operation, Any background of Propofol or Midazolam sensitivity, Need for additional treatment, Becoming ill after surgery, Increased anesthesia level, Respiratory distress, Patients of class 3 and 4 of ASA, Hemodynamic disorders

Age
 From **15 years** old to **60 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **42**

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

Ethics Committee of Jahrom University of Medical Sciences

Street address

7414846199, Motahari Street, Jahrom University of Medical Sciences, Jahrom, Fars, Iran

City

Jahrom

Postal code

7414846199

Approval date

2013-05-29, 1392/03/08

Ethics committee reference number

jums.rec.1392.005

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

k91.9

ICD-10 code description

Postprocedural disorder of digestive system, unspecified

Primary outcomes

1

Description

Nausea and Vomiting

Timepoint

1 ,3, 5, 10, 15, 30 and 60 minutes after spinal anesthesia

Method of measurement

Have or not have with the Questionnaire made by Investigator

Secondary outcomes

1

Description

Blood pressure

Timepoint

1, 3, 5, 10, 15, 30 and 60 minutes after spinal anesthesia

Method of measurement

Sphygmomanometer

2

Description

Pulse

Timepoint

1, 3, 5, 10, 15, 30 and 60 minutes after spinal anesthesia

Method of measurement

Pulse oximetry

3

Description

Respiratory Rate

Timepoint

1, 3, 5, 10, 15, 30 and 60 minutes after spinal anesthesia

Method of measurement

Counting breaths by investigator

4

Description

O2 Saturation of arterial blood

Timepoint

During surgery and recovery

Method of measurement

Pulse oximetry

5

Description

Apgar

Timepoint

1 and 5 minutes after the birth

Method of measurement

Assessment by investigator by Apgar criteria

Intervention groups

1

Description

Patients were divided into two groups A and B randomly by Random Allocation software. They did not receive any special medicine before entering operation room. Before starting surgery, patients received 7 ml/kg Ringer serum and then While patients got 65 mg Lidocain 5% for spinal anesthesia, group A were injected 1.5mg Midazolam. At the end of surgery patients were transferred to the recovery room. They were kept in recovery room for at least 1 hour. Nausea and vomiting of patients were measured based on their feelings in 1, 3, 5, 10, 15, 30 and 60 minutes after spinal anesthesia by a self-instructive questionnaire. The patients and the investigator did not have any information about the drugs used.

Category

Prevention

2

Description

Patients were divided into two groups A and B randomly by Random Allocation software. They did not receive any special medicine before entering operation room. Before starting surgery, patients received 7 ml/kg Ringer serum and then While patients got 65 mg Lidocain 5% for spinal anesthesia, group B were injected 2cc (20mg) Propofol. At the end of surgery patients were transferred to the recovery room. They were kept in recovery room for at least 1 hour. Nausea and vomiting of patients were measured based on their feelings in 1, 3, 5, 10, 15, 30 and 60 minutes after spinal anesthesia by a self-instructive questionnaire. The patients and the investigator did not have any information about the drugs used.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital affiliated with the University of Medical Sciences

Full name of responsible person

Marjan Jaladat

Street address

7414846199, Motahari Street, Jahrom University of Medical Sciences, Jahrom, Fars, Iran

City

Jahrom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Jahrom University of Medical Sciences

Full name of responsible person

Kavoos Solh joo

Street address

7414846199, Motahari Street, Jahrom University of Medical Sciences, Jahrom, Fars, Iran

City

Jahrom

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, Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

Marjan Jaladat

Position

Medical Student

Other areas of specialty/work

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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