Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Comparison Effect of Propofol and Ketamine On complications after Cesarean Section under Spinal Anesthesia

Protocol summary

Summary

The propose of this study is assess the competitive effect of propofol and ketamin on complication after cesarean under spinal anesthesia during the year 2015. The statistical population included women candied of cesarean elective and sample size is 92. Inclusion criteria : age 18-35; term pregnancy; same surgeon and anesthesia; same dose of spinal anesthesia drug. The exclusion criteria : administration of general anesthesia drug in the absence of adequate spinal anesthesia ; systemic disease.In a randomized double blind clinical trial [blind for patients and researcher] the patients is assigned into four group: Placebo, propofol, ketamin and propofol plus ketamin. The parameters of pain, shivering, nausea and vomiting and drug consumption will be assessed with checklist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061514668N4**
Registration date: **2015-09-18, 1394/06/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-09-18, 1394/06/27

Registrant information

Name

Molouk Jaafarpour

Name of organization / entity

Ilam University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

jaafarpour-m@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Science

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison Effect of Propofol and Ketamine On complications after Cesarean Section under Spinal Anesthesia

Public title

The Comparison Effect of Propofol and Ketamine On complications after Cesarean Section under Spinal Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria : age 18-35; term pregnancy; same surgeon and anesthesia; same dose of spinal anesthesia drug. exclusion criteria : administration of general anesthesia drug; systemic disease

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

samples with Sealed envelope technique assigned in groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Ilam University of Medical Science

Street address

Pajohesh Blvd, Banganjab, Ilam

City

Ilam

Postal code

Approval date

2015-06-08, 1394/03/18

Ethics committee reference number

IR.MEDILAM.EC/94/H/277

Health conditions studied

1

Description of health condition studied

post cesarean complications

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section, unspecified

Primary outcomes

1

Description

pain

Timepoint

1,4,8,12 and 24 hrs after surgery

Method of measurement

Visual Analogue Scale (VAS) and checklist

2

Description

shivering

Timepoint

During recovery

Method of measurement

checklist and VAS

3

Description

Nausea & Vomiting

Timepoint

During recovery

Method of measurement

checklist and VAS

Secondary outcomes

1

Description

Brest feeding time

Timepoint

after surgery

Method of measurement

hrs

Intervention groups

1

Description

Intervention group : In propofol group 0.25 mg/kg will be injected interavenos after clamping of umbilical cord and fetus expulsion

Category

Treatment - Drugs

2

Description

Intervention group: In ketamin group 0.25 mg/kg will be injected interavenos after clamping of umbilical cord and fetus expulsion.

Category

Treatment - Drugs

3

Description

Intervention group: In ketofol group 25 mg propofol pulse 25 mg ketamin will be injected interavenos after clamping of umbilical cord and fetus expulsion.

Category

Treatment - Drugs

4

Description

Control group: In placebo group normal saline will be injected interavenos after clamping of umbilical cord and

fetus expulsion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mostafa Khomeini Hospital

Full name of responsible person

Molouk Jaafarpour

Street address

Ilam University of Medical Science

City

Ilam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ilam University of Medical Science

Full name of responsible person

Dr Koroosh Soleimannejad

Street address

Pajohesh Blvd, Banganjab

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Ilam

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 of Ilam University of Medical Science

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

Ilam University of Medical Science

Full name of responsible person

Molouk Jaafarpour

Position

Lecturer, Academic Member

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