

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of Propofol and Midazolam on post partum maternity blues after cesarean delivery in women referring to Kerman Afzalipour hospital in 2016-2017

Protocol summary

Study aim

The effects of Propofol and Midazolam on postpartum maternity blues after cesarean delivery in women referring to Kerman Afzalipour hospital in 2016-2017

Design

In this clinical trial with control group, parallel group and double blinded, patients randomly divided in two groups (100 patients in each group) using statistical software (random allocation sequence). first group received Propofol and Midazolam administrated for patients in control group.

Settings and conduct

This study was conducted in Kerman Afzalipour hospital and patients, physician and data analysor were masked.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with cesarean indication Exclusion criteria: Using antidepressants drugs; Experience of other psychological problems under treatment; Experience of acutely debilitating or life-threatening illnesses; Drug abuse or incitement to any form; Development of anesthesia complications during cesarean section; Stillbirth during cesarean section

Intervention groups

In this study patients in intervention group received Propofol and patients in control group received Midazolam after delivery.

Main outcome variables

Postpartum maternity blues

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190819044559N2**

Registration date: **2019-11-07, 1398/08/16**

Registration timing: **retrospective**

Last update: **2026-06-28, 1405/04/07**

Update count: **1**

Registration date

2019-11-07, 1398/08/16

Registrant information

Name

Morteza Hashemian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3223 5011

Email address

mortezahashemian@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2018-03-16, 1396/12/25

Actual recruitment start date

2017-04-04, 1396/01/15

Actual recruitment end date

2018-02-15, 1396/11/26

Trial completion date

2018-02-15, 1396/11/26

Scientific title

The effect of Propofol and Midazolam on post partum maternity blues after cesarean delivery in women referring to Kerman Afzalipour hospital in 2016-2017

Public title

The effect of Propofol and Midazolam on post partum maternity blues

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women with cesarean indication

Exclusion criteria:
Using antidepressants drugs Experience of other psychological problems under treatment Experience of acutely debilitating or life-threatening illnesses Drug abuse or consumption of incitement medications in any form Development of anesthesia complications during the cesarean section stillbirth during the cesarean section

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

Gender
Female

Phase
1

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **200**
Actual sample size reached: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study patients randomly divided to intervention and control groups (100 patients in each group) using random allocation sequence with SAS statistical software. according to this method, a simple randomization list product and patients` involvement in each group determine base on their order entry. we used Sequentially numbered, sealed, opaque envelopes for allocation concealment. patients (individuals) were the randomization units.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients, main investigator and data analyser were masked of patients allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Jahad blvd., Ebn-e Sina ST., Vice-Chancellor of Research of Kerman University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2017-04-03, 1396/01/14

Ethics committee reference number

KMU.IR.REC.1396.1267

Health conditions studied

1

Description of health condition studied

post partum maternity blues

ICD-10 code

F53.0

ICD-10 code description

Mental and behavioural disorders associated with the puerperium, not elsewhere classified

Primary outcomes

1

Description

Postpartum maternity blues

Timepoint

After Cesarean section in recovery, two days after cesarean section, two weeks after cesarean section

Method of measurement

Edinburg questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving 20-75µg/kg/min Propofol after delivery using infusion pump.

Category

Treatment - Other

2

Description

Control group: receiving 1-2 mg Midazolam after delivery, Single dose

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Morteza Hashemian

Street address

Imam Khomeyni highway, close to Shahid Bahonar University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Morteza Hashemian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available