Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 highwey, close to Shahid Bahonar University

City
Kerman

Province
Kerman

Postal code
7616913911

Phone
+98 34 3132 8000

Email
mortezahashemian@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Abbas Pardakhty

Street address
Jahad blvd., Ebn-e Sina st.

City
Kerman

Province
Kerman

Postal code
7619813159

Phone
+98 34 3226 3855

Email
Abpardakhty@kmu.ac.ir

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
Anesthesiology

Street address
Jomhori Eslami blvd., vice chancellor of treatment

City
Kerman

Province
Kerman

Postal code
7618747653

Phone
+98 34 3211 3012

Email
mortezahashemian@kmu.ac.ir

Person responsible for scientific 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
Anesthesiology

Street address
Gharani st. Shahid Bahonar hospital

City
Kerman

Province
Kerman

Postal code
7618747653

Phone
+98 34 3223 5011

Fax

Email
mortezahashemian@kmu.ac.ir

Person responsible for updating data

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
Anesthesiology
Street address
Gharani st. Shahid Bahonar hospital
City
Kerman
Province
Kerman
Postal code
7618747653
Phone
+98 34 3223 5011
Fax
Email
mortezahashemian@kmu.ac.ir

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