Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Bispectral index Monitoring on recovery from anesthesia and early postanesthetic complication after cesarean section

Protocol summary

Summary

This randomized clinical trials , dubel-blind study aims to investigate the effects of aesthesia depth monitoring on the recovery and post-operative complications of cesarean candidates in the ward and recovery on 68 patients in the case and control groups who have inclusion criteria during 4 months will be down. In both groups, the beginning of anesthesia is similar; however, infusion of anesthetic drug is with Bispectral Index (BIS) in the case group and by the conventional routine in the control group. At the end of surjery, anesthetic drugs will be stopped, and the time of extubation, recovery time, nausea, vomiting, shivering, and agitation in the recovery, and 6 hours after operation will be compared. Moreover, awareness during operation will be assessed 24 hours after the operation by a questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080218643N1**
Registration date: **2014-11-28, 1393/09/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-11-28, 1393/09/07

Registrant information

Name

Rajab Arbabpour

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3231 6829

Email address

arbabpor@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2014-09-06, 1393/06/15

Expected recruitment end date

2015-01-05, 1393/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Bispectral index Monitoring on recovery from anesthesia and early postanesthetic complication after cesarean section

Public title

Effects of aesthesia deep monitoring on the recovery of cesarean candidates

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Natural pregnancy; 20-35 years of age; Elective cesarean; No drug use 48 hours before operation, except for iron, folic acid, and multi-vitamins; No history of diabetes, pre-eclampsia, eclampsia, hyperthyroidism, hypothyroidism, heart and renal problem, asthma, mental and psychological disorders, and addiction. Exclusion criteria: cesarean section duration over 45 min; Need for changes anesthesia method; Emergency situation for the mother or child; Suspect of the indicated depth according to the physician in the intervention group, and thus change in anesthesia

method

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

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

Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghaffari St., Birjand, Sothern Khorasan

City

Birjand

Postal code

Approval date

2014-07-05, 1393/04/14

Ethics committee reference number

03-04-1393

Health conditions studied

1

Description of health condition studied

Elective cesarean

ICD-10 code

O82

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

Propofol dose needed for patients

Timepoint

Drug use calculation Immediately after operation

Method of measurement

Based on received drug min/kg

Secondary outcomes

1

Description

Postoperative complication (nausea, vomiting, shivering, and agitation)

Timepoint

During 24 hours after operation for complication

Method of measurement

Questionnaire / interview

Intervention groups

1

Description

Case group: The intervention group dose of anesthesia drug will be regulated in the base of BIS

Category

Other

2

Description

Control group: Controls receive the conventional anesthesia drugs.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-asr Hospital in Birjand

Full name of responsible person

Rajab Arbabpour

Street address

Operating room, Vali-asr Hospital, Ghaffari St., Birjand, Sothern Khorasan

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Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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Vali-asr Hospital, Ghaffari St., Birjand, Sothern Khorasan

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Rajab Arbabpour

Position

Master of Nursing

Other areas of specialty/work

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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