

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of depth of anesthesia with Midazolam+ Na Thiopental and Midazolam +Propofol in cesarean section

Protocol summary

Summary

This study is designed for comparison of the depth of anesthesia with midazolam + Na thiopental and Midazolam + Propofol in cesarean section. 50 parturient will be operated under general anesthesia and depth of anesthesia will be measured by BIS. Major inclusion criteria are: parturient undergoing elective C/S ,age range 18-40 ,ASA Class I,II and Mallampati Class I,II and major exclusion criteria are: history of respiratory and cardiovascular disease,HTN, addiction, multiple gestation emergency C/S, predicted difficult airway.Primary outcome is depth of anesthesia. The patients are divided in two groups in from of double blind , both receive metoclopramide , 10mg,I.V, Midazolam 1.5mg IV and Lidocaine 1mg/kg I.V.Induction of general anesthesia and tracheal intubation(size 7,cuffed) with cricoids pressure is carried out in first group by Na thiopental 5mg/kg and succinylcholine 1.5 mg/kg and in second group by propofol 2.5mg/kg and succinylcholine 1.5mg/kg (Rapid sequence induction) BIS values as well as hemodynamic parameters is recorded at the time of standard monitoring installation , just before induction, after induction(just before laryngoscopy) 5 minutes after delivery and administering 1.5microg/kg fentanyl and 0.1 mg /kg morphine (I.V), when discontinuing volatile anesthetics and during extubation. The measures of two groups is compared there after. If hemodynamic instability or lightening of anesthesia occurred we will treat with appropriate intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105296625N1**

Registration date: **2011-06-27, 1390/04/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-27, 1390/04/06

Registrant information

Name

Mozaffar Rabiee

Name of organization / entity

Babool university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor Of Research Babol University Of Medical Science

Expected recruitment start date

2011-04-21, 1390/02/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of depth of anesthesia with Midazolam+ Na Thiopental and Midazolam +Propofol in cesarean section

Public title

Comparison of depth of anesthesia with Midazolam+ Na Thiopental and Midazolam +Propofol in cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion Criteria: patients undergoing elective C/S; age range 18-40; ASA Class I,II; Mallampati class I,II Exclusion Criteria : History of respiratory and cardiovascular diseases; HTN; Addiction; Multiple Gestation; Emergency C/S; Predicted difficult airway

Age
 From **18 years** old to **40 years** old

Gender
 Female

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **50**

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
 Ethical Council of Babol University Of Medical Sciences
Street address
 Ganjafrooz Avenue, Daneshgah Square , Ruhani Hospital
City
 Babol
Postal code
Approval date
 2011-02-15, 1389/11/26
Ethics committee reference number
 3045/30/پ/ژ

Health conditions studied

1

Description of health condition studied
 General anesthesia in Cesarean section
ICD-10 code
 074
ICD-10 code description

Complications of anaesthesia during labour and delivery

Primary outcomes

1

Description
 Depth of anesthesia
Timepoint
 before intervention until end of surgery and extubation
Method of measurement
 By Bispectral Index System

Secondary outcomes

1

Description
 BIS Values
Timepoint
 At time of lying on surgical table, Induction , Intubation, Skin incision, 5 min after delivery and administering narcotics, discontinuing volatile anesthetics and extubation
Method of measurement
 By Bispectral Index System

2

Description
 Hemodynamic parameters
Timepoint
 At time of lying on surgical table, Induction , Intubation, Skin incision, 5 min after delivery and administering narcotics, discontinuing volatile anesthetics and extubation
Method of measurement
 ECG, Pulse oximeter, Sphygmomanometer

3

Description
 newborn APGAR Score
Timepoint
 1 and 5 min after delivery
Method of measurement
 Visual -Examination

4

Description
 PH and Blood Gases in newborn umbilical Artery
Timepoint
 After delivery
Method of measurement
 Arterial Blood Gas

Intervention groups

1

Description

Metoclopramide 10mg , Midazolam 1.5 mg , lidocaine 1.5mg/kg+ Propofol 2.5 mg/kg+ Succinyl choline 1.5 mg/kg IV, single Dose

Category

Other

2

Description

Metoclopramide 10mg , Midazolam 1.5 mg , lidocaine 1.5mg/kg+ Na thiopental 5 mg/kg+ Succinyl choline 1.5 mg/kg IV, single Dose

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ruhani Medical & Educational Center

Full name of responsible person

Dr Seyed Mozaffar Rabiee

Street address

Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrroz Avenue, Babol

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor Of Research Babol University Of Medical Science

Full name of responsible person

Dr Amrolah Mostafanejad

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrroz Avenue, Babol

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor Of Research Babol 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

Babol University Of Medical Sciences

Full name of responsible person

Dr Seyed Mozaffar Rabiee

Position

Assistant Professor Of Anesthesiology

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