

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 8296

Email address

m_rabiee@mubabol.ac.ir

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

O74

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, Ganjafrooz 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, Ganjafrooz 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

Street address

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

City

Babol

Postal code

Phone

+98 11 1223 8296

Fax

Email

drm_rabiee@yahoo.com

Web page address

Person responsible for scientific 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

Street address

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

City

Babol

Postal code

Phone

+98 11 1223 8296

Fax

Email

drm_rabiee@yahoo.com

Web page address

Person responsible for updating data

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

Street address

Anesthesiology Department, Ruhani Hospital,

Daneshgah Square, Ganjafrooz Avenue, Babol

City

Babol

Postal code

Phone

Fax

Email

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