

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The comparison of propofol , thiopental with thiopental- propofol as induction drug on hemodynamic parameters of parturients and neonatal apgar during elective cesarean section

Protocol summary

Summary

This is a randomized clinical trial to evaluate the effect of propofol, thiopental sodium and the combination of two drugs on neonatal apgar and hemodynamic parameters of in elective cesarean section. This study was done on pregnant women who were candidates for elective cesarean section and referred to Valiasr Hospital of Birjand. Inclusion criteria: Pregnant women with normal fetus and anesthesia class 1, 2. After the selection inclusion criteria the 84 patients were randomly divided into three groups of 28 subjects (propofol, thiopental sodium, thiopental sodium and propofol combined) groups. In the propofol group, propofol 2 mg /kg, in the thiopental group thiopental 4 mg /kg and thiopental and propofol combined group propofol 1 mg /kg, thiopental 2 mg /kg were administered Intravenous. First and fifth minute Apgar score was recorded. Also, the maternal hemodynamic parameters were measured before induction of anesthesia, after intubation for 12 minutes once every 3 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201503166808N6**

Registration date: **2015-11-19, 1394/08/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-11-19, 1394/08/28

Registrant information

Name

Maryam Tolyat

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 1444 9056

Email address

tolyatm@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2015-02-09, 1393/11/20

Expected recruitment end date

2015-06-10, 1394/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of propofol , thiopental with thiopental-propofol as induction drug on hemodynamic parameters of parturients and neonatal apgar during elective cesarean section

Public title

The effect of anesthesia on apgar score and maternal hemodynamic parameters after cesarean

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA Class 1 and 2; candidate for elective cesarean section; fetus is normal and full term.
Exclusion criteria: drug use by the mother; prolonged

surgery; fetal abnormalities

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

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, Street
Ghaffari, Birjand, Jonoubi Khorasan, Iran

City

Birjand

Postal code**Approval date**

2015-02-05, 1393/11/16

Ethics committee reference number

1009

Health conditions studied**1****Description of health condition studied**

caesarean

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes**1****Description**

Apgar score

Timepoint

First and fifth minute Apgar score

Method of measurement

Apgar test

2**Description**

Blood pressure

Timepoint

before induction of anesthesia, after intubation for 12
minutes once every 3 minutes

Method of measurement

Blood pressure device

3**Description**

pulse

Timepoint

before induction of anesthesia, after intubation for 12
minutes once every 3 minutes

Method of measurement

Monitoring device

4**Description**

Oxygen saturation

Timepoint

before induction of anesthesia, after intubation for 12
minutes once every 3 minutes

Method of measurement

Pulse oximeter

Secondary outcomes

empty

Intervention groups**1****Description**

In propofol group, propofol 2 mg /kg Intravenous for
induction

Category

Treatment - Drugs

2**Description**

The thiopental group thiopental 4 mg /kg Intravenous for
induction

Category

Treatment - Drugs

3**Description**

The thiopental and propofol combined group propofol 1
mg /kg , thiopental 2 mg /kg Intravenous for induction

Category

Treatment - Drugs

Birjand University of Medical Sciences, Street Ghaffari, Birjand, Jonoubi Khorasan, Iran

Recruitment centers**1****Recruitment center****Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Malihe Zanguoie

Street address

Valiasr Hospital, Street Ghaffari, Birjand, Jonoubi Khorasan, Iran

City

Birjand

City

Birjand

Postal code**Phone**

+98 56 3239 5453

Fax**Email**

tolyatm@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Maryam Tolyat

Position

MSc in Nursing

Other areas of specialty/work**Street address**

Birjand University of Medical Sciences, Street Ghaffari, Birjand, Jonoubi Khorasan, Iran

City

Birjand

Postal code**Phone**

+98 56 3239 5453

Fax**Email**

tolyatm@yahoo.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Gholamreza Sharifzaadeh

Street address

Birjand University of Medical Sciences, Street Ghaffari, Birjand, Jonoubi Khorasan, Iran

City

Birjand

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

Maryam Tolyat

Position

MSc in Nursing

Other areas of specialty/work**Street address****Person responsible for updating data****Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Maryam Tolyt

Position

MSc in Nursing

Other areas of specialty/work**Street address**

Birjand University of Medical Sciences, Street Ghaffari, Birjand, Jonoubi Khorasan, Iran.

City

Birjand

Postal code**Phone**

+98 56 3239 5453

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