

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparison of depth of anesthesia in induction with sodium thiopental & propofol in elective cesarean section by BIS, IFT

#### Protocol summary

##### Summary

Objective: To compare the Depth of Anesthesia in induction with Sodium Thiopental & Propofol in Elective Cesarean Section by BIS, IFT. Inclusion criteria: 90 pregnant women (ASA I- II) who are under general anesthesia for elective cesarean section. Exclusion criteria: Patients who are not properly cooperate; prior use of sulfate MgSO<sub>4</sub>; mental disorders; a history of previous awareness during general anesthesia, taking blood pressure medication or vasodilators or vasodepressor and human stimulant or psychotropic drugs; multiple gestation or preterm labor; fetal distress; neuromuscular diseases, opium addicts; history of multiple drug allergies or sensitivity to anesthetics; bradycardia and heart block. Intervention: 90 patients divided into two groups P or T: Anesthesia will induce by Thiopental (5-4 mg / kg) in group T and Propofol (2.5-2 mg / kg) in group P and Scholin (2 mg / kg) and is going to maintain with 50% N<sub>2</sub>O, O<sub>2</sub>, Sevoflurane 2% and after birth by N<sub>2</sub>O 50%, O<sub>2</sub>, sevoflurane 1.2%, a blood pressure cuff will fasten on the dominant arm and inflated (200 mmHg) immediately before administering the drugs. After induction, a recorded message will be played once by the headphones every 1 minute to move the fingers of the dominant hand. Hand movement will be scored as follows after playing message: No movement: zero /uncertain movements: open and close the fingers: 2 before induction of anesthesia, BIS sensor device will be installed according to the manufacturer's instructions on the forehead of the patient. BIS values and IFT following events will be recorded at baseline, Induction of anesthesia, laryngoscopy and intubation, Skin incision, opening the peritoneum, Uterine incision, childbirth Uterine closure, , tying the layers under the skin, Subcutaneous closures, skin closure, turn off the gas anesthesia, eye opening and extubation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016082819470N44**

Registration date: **2016-12-21, 1395/10/01**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-21, 1395/10/01

##### Registrant information

##### Name

Farzaneh Masihi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3647 4270

##### Email address

masihif@sums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice chancellor for research, Shiraz University of Medical Science

##### Expected recruitment start date

2016-11-10, 1395/08/20

##### Expected recruitment end date

2017-08-23, 1396/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison of depth of anesthesia in induction with sodium thiopental & propofol in elective cesarean section by BIS, IFT

**Public title**

Comparison of depth of anesthesia in induction with sodium thiopental & propofol in elective cesarean section by BIS, IFT

**Purpose**

Diagnostic

**Inclusion/Exclusion criteria**

Inclusion criteria: 90 pregnant women (ASA I- II) who are under general anesthesia for elective cesarean section. Exclusion criteria: Patients who are not properly cooperate; patients who received magnesium sulfate MgSO<sub>4</sub> before the study; mental disorders; Patients who have a history of previous awareness during general anesthesia, patients who take blood pressure medication or patients who require the use of vasodilators or vasodepressor drugs; patients who consume human stimulant or psychotropic drugs; mothers with multiple gestation or preterm labor; fetal distress, patients with neuromuscular diseases, opium addicts; history of multiple drug allergies or sensitivity to anesthetics; patients with bradycardia and heart block.

**Age**

No age limit

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 90

**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**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Vice Chancellor of research, Shiraz University of

Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

**City**

Shiraz

**Postal code****Approval date**

2014-11-16, 1393/08/25

**Ethics committee reference number**

CP-P-9364-6484

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

caesarean section

**ICD-10 code**

082.0

**ICD-10 code description**

Delivery by elective caesarean section

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

To determine the depth of the anesthesia by Sodium Thiopental and Propofol as an induction anesthetic

**Timepoint**

at baseline, Induction of anesthesia, laryngoscopy and intubation, Skin incision, opening the peritoneum, Uterine incision, childbirth Uterine closure, , tying the layers under the skin, Subcutaneous closures, skin closure, turn off the gas anesthesia, eye opening and extubation.

**Method of measurement**

bispectral index (BIS) and Isolated forearm technique (IFT)

**Secondary outcomes**

empty

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

Group T: Anesthesia will induce by rapid sequence method with administration of Thiopental (5-4 mg / kg) in group T and Scholine (2 mg / kg) and cricoid pressure. Anesthesia until the birth will maintain with 50% N<sub>2</sub>O, O<sub>2</sub>, Sevoflurane 2% and after birth by N<sub>2</sub>O 50%, O<sub>2</sub>, sevoflurane 1.2%, midazolam 0.03 mg / kg, morphine 0.1 mg / kg and Cisatracurium 0.04 mg / kg for muscle relaxation.

**Category**

Treatment - Drugs

**2****Description**

Group P: Anesthesia will induce by rapid sequence method with administration of Propofol (2.5-2 mg / kg) in group P and Scholine (2 mg / kg) and cricoid pressure. Anesthesia until the birth will maintain with 50% N2O, O2, Sevoflurane 2% and after birth by N2O 50%, O2, sevoflurane 1.2%, midazolam 0.03 mg / kg, morphine 0.1 mg / kg and Cisatracurium 0.04 mg / kg for muscle relaxation.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hafez Hospital

##### Full name of responsible person

Maryam Beihaghi

##### Street address

Hafez Hospital, Chamran Boulevard

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for Research, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Seed Basir Hashemi

##### Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

##### City

Shiraz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice Chancellor for Research, Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Maryam Beihaghi

##### Position

anesthesiology resident/physician

##### Other areas of specialty/work

##### Street address

Anesthesiology Department- Faghihi Hospital- Zand Street

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+98 71 3647 4270

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beihaghi@sums.ac.ir

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Hadavi

##### Position

Anesthesiologist

##### Other areas of specialty/work

##### Street address

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Farzaneh Masihi

##### Position

MS in english teaching ,BS in anesthesia/English Consultant

##### Other areas of specialty/work

##### Street address

5th floor, Mohammad Rasul Allah Research Tower, Khalili Street

##### City

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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