

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of two different doses of thiopental sodium in elective cesarean section (C/S) under general anesthesia on depth of anesthesia with Isolated Forearm Technique (IFT) and on neonatal neurobehavioral test

Protocol summary

Study aim

Objective: Comparison of two different doses of thiopental sodium in elective cesarean section (C/S) under general anesthesia on depth of anesthesia with Isolated Forearm Technique (IFT) and on neonatal neurobehavioral test

Design

Double blind randomized clinical trial

Settings and conduct

patients divided into two groups one or two in the Hafeiz Hospital. Induction of anesthesia will be with Thiopental (5mg / kg) in group one and Thiopental (7 mg / kg) in group two and Scholin (2 mg / kg), maintenance was with 50% N2O, 50% O2, Sevoflurane and after birth by N2O 50%, O2 50%, sevoflurane.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 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 MgSO4; mental disorders; a history of previous awareness during general anesthesia, taking blood pressure medication or vasodilators or vasodepressor and human stimulant or psychotropic drugs; neuromuscular diseases, opium addicts; detection of any fetal abnormalities by ultrasonography.

Intervention groups

80 patients divided into two groups: Induction of anesthesia will be with Thiopental (5mg / kg) in group one and Thiopental (7 mg / kg) in group two and Scholin (2 mg / kg), maintenance was with 50% N2O, 50% O2, Sevoflurane and after birth by N2O 50%, 50%, sevoflurane.

Main outcome variables

The depth of the anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082819470N45**

Registration date: **2017-07-28, 1396/05/06**

Registration timing: **prospective**

Last update: **2019-03-13, 1397/12/22**

Update count: **1**

Registration date

2017-07-28, 1396/05/06

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 Sciences

Expected recruitment start date

2017-08-25, 1396/06/03

Expected recruitment end date

2017-11-24, 1396/09/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of two different doses of thiopental sodium in elective cesarean section (C/S) under general anesthesia on depth of anesthesia with Isolated Forearm Technique (IFT) and on neonatal neurobehavioral test

Public title
Comparison of two different doses of thiopental sodium in elective cesarean section (C/S) under general anesthesia on depth of anesthesia with Isolated Forearm Technique (IFT) and on neonatal neurobehavioral test

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Aged between 15-50 pregnant women undergoing cesarean section ASA I-II
Exclusion criteria:
Patients who are not properly cooperate Prior use of sulfate MgSO4 Mental disorders History of previous awareness during general anesthesia Taking blood pressure medication or vasodilators or vasodepressor and human stimulant or psychotropic drugs Neuromuscular diseases Opium addiction Fetal abnormalities by ultrasonography

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
An anesthesia nurse is providing the Thiopental syringe to the anesthesiologist for induction of anesthesia .The anesthesiologist who are responsible for injecting Thiopental is aware of the study groups while the another anesthesiologist who will assess the mothers and infants during the study is unaware of the study groups .

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

Province

Fars

Postal code

7194734786

Approval date

2014-11-16, 1393/08/25

Ethics committee reference number

CT-P-9362-6822

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, uterine retraction, childbirth, Uterine closure, tying the layers under the skin, Subcutaneous closures, at the start of skin closure, 2 minutes after skin closure, eye opening and extubation.

Method of measurement

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

Secondary outcomes

1

Description

neonate Apgar

Timepoint

at 0, 5, and 20 minutes after birth

Method of measurement

Apgar score

2**Description**

Neurobehavioral test

Timepoint

20 minutes after birth

Method of measurement

Neurobehavioral test

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

Group one: Anesthesia will induce with administration of Thiopental (5 mg / kg) in group one and Scholine (2 mg / kg) will maintain with 50% N2O, O2, Sevoflurane and by N2O 50%, O2, sevoflurane after birth.

Category

Treatment - Drugs

2**Description**

Group two: Anesthesia will induce with administration of Thiopental (7mg / kg) in group one and Scholine (2 mg / kg) will maintain with 50% N2O, O2, Sevoflurane and by N2O 50%, O2, sevoflurane after birth.

Category

Treatment - Drugs

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

Hafez Hospital

Full name of responsible person

Fateme Mirhadi

Street address

Dansho square, Chamran blvd.

City

Shiraz

Province

Fars

Postal code

7194634786

Phone

+98 71 3647 9531

Email

Hafez@sums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

SACRC@sums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Mirhadi

Position

anesthesiology resident/physician

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7187686964

Phone

+98 71 3647 4270

Fax

Email

fateme.mirhadi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Golnar Sabetian

Position

Anesthesiologist/ICU Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Fax

Email

gsabetian@yahoo.com

Web page address

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

Latest degree

Master

Other areas of specialty/work

Others

Street address

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

City

Shiraz

Province

Fars

Postal code

7134944119

Phone

+98 71 3647 4270

Fax

Email

masihifarzaneh@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available