Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 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

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Iran (Islamic Republic of)

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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
Danshjo square, Chamran blvd.
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7194634786
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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
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7134844119
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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
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Position

Anesthesiologist/ICU Fellowship

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Subspecialist

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Person responsible for updating data

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MS in english teaching ,BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Others

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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