

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of General Anesthesia with Thiopental Sodium and Propofol on the 1 and 5 minute Apgar newborns by Cesarean

Protocol summary

Study aim

Effect of General Anesthesia with Thiopental Sodium and Propofol on the 1 and 5 minute Apgar newborns by Cesarean

Design

The required number of samples in each group is 50, and a total of 100 people are in both groups. In group A, for induction of anesthesia, 2.5 mg / kg propofol was used and in the group B 4 mg / kg Thiopental Sodium was used. Muscle Paralyzed for intubation was supplied by succinylcholine and maintenance of anesthesia with isoflurane 0.5 % And a mixture of oxygen and nitrous oxide are used. Atracurium is used in each group to maintain muscle relaxation. Examples of anesthesia induction intervals until embryo outflow is greater than 10 minutes or the interval between the uterus and the embryo is longer than 3 minutes are excluded. . In each group in the thirty seconds after the birth of the 5 heart rate factors - the condition of breathing and skin-tone of the muscle Reflex response ANIs are evaluated by the midwife whose currency is the type of medication and is recorded on the checklist. The presence of nausea and vomiting during recovery is recorded by a recovery nurse.

Settings and conduct

OR of shahidan mobini Hospital in sabzevar city

Participants/Inclusion and exclusion criteria

AGE 18-35, ASA I ,II

Intervention groups

Pregnant women are divided randomly into two groups of thiopental sodium and propofol between the age of 18-35 under cesarean section.

Main outcome variables

1) Thiopental is effective on the first minute Apgar score in infants undergoing cesarean section surgery. 2) Thiopental is effective on the fifth minute apgar of neonates during cesarean section surgery. 3) Propofol affects the first-ever Apgar score of neonates in cesarean section surgery. 4) Propofol affects the 5th minute Apgar

score in infants undergoing cesarean

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180307038985N1**

Registration date: **2018-05-15, 1397/02/25**

Registration timing: **retrospective**

Last update: **2018-05-15, 1397/02/25**

Update count: **0**

Registration date

2018-05-15, 1397/02/25

Registrant information

Name

Manijeh Yousefi Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 8595

Email address

yousefim@medsab.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2017-07-21, 1396/04/30

Trial completion date

empty

Scientific title

Effect of General Anesthesia with Thiopental Sodium and Propofol on the 1 and 5 minute Apgar newborns by Cesarean

Public title

Effect of General Anesthesia with Thiopental Sodium and Propofol on the 1 and 5 minute Apgar newborns by Cesarean

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

age 18-35, ASA I, II

Exclusion criteria:

Diabet, over weight, addiction, bleeding, heart disease, pregnancy hypertention

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple

Blinding (investigator's opinion)

Double blinded

Blinding description

detector, analyzer

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Azimian

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Approval date

2017-04-21, 1396/02/01

Ethics committee reference number

ir.medsab.rec.1396.86

Health conditions studied

1

Description of health condition studied

Effect of general anesthesia on first and fifth minutes of Apgar in cesarean section

ICD-10 code

P91.8

ICD-10 code description

Other specified disturbances of cerebral status of newborn

Primary outcomes

1

Description

NeonateApgar

Timepoint

First &Fifth Min After Birth

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group": pofol, The dose of propofol is 5-2.5 mg / kg bolus and its maintenance dose is 300-100 mg / kg (once a kg / min). Continuous infusion is 1% solution ready for reconstitution.

Category

Treatment - Drugs

2

Description

Control group: Thiopental, The dose of Thiopental Sodium 5-3 mg / kg is given intravenously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahidan Mobini Hospital
Full name of responsible person
DR Manijeh Yousefi Moghadam
Street address
Kashefi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Manijeh Yousefi Moghadam
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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
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
ManijehYousefi Moghadam
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

By sending an email

When the data will become available and for how long

After the article is published

To whom data/document is available

Author's email address

Under which criteria data/document could be used

For scientific research

From where data/document is obtainable

Author's email address

What processes are involved for a request to access data/document

E-mail

Comments