

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of general anesthesia and spinal anesthesia on serum cytokines in cesarean section patients

Protocol summary

Study aim

The aim of this study was to measure the serum levels of cytokines including interleukin 6, interleukin 10 and TNF α in general and spinal anesthesia and compare them with each other in cesarean section.

Design

Clinical trial, with a parallel group design, with blinded outcome assessment, randomized using random number table, performs on 30 patients between April 2020 and March 2021.

Settings and conduct

30 patients undergoing cesarean section who refer to Taleghani Hospital are randomly assigned into two similar groups of 15 people of spinal anesthesia and general anesthesia. In the spinal anesthesia group, 2.8 cc of 0.5% Marcaine is injected into the L3-L4 or L4-L5 space. In the general anesthesia group, endotracheal intubation is performed with thiopental 4-6 mg / kg and succinylcholine 1-1.5 mg / kg . It is then continued with nitrous oxide 50 % and 0.8% isoflurane. After delivery of baby, fentanyl 200 μ g per 70 kg is injected. Both groups are given two diclofenac suppositories of 100 mg after anesthesia to control postoperative pain.

Participants/Inclusion and exclusion criteria

All patients scheduled for cesarean section, who have completed the consent form and are ASA Class I, II, are included in the study. Patients with coagulation disorders and phospholipid syndrome are excluded from the study.

Intervention groups

Two groups of general and spinal anesthesia .

Main outcome variables

Interlukin-6: Interlukin10: TNF α

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200930048887N1**

Registration date: **2020-10-13, 1399/07/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-13, 1399/07/22**

Update count: **0**

Registration date

2020-10-13, 1399/07/22

Registrant information

Name

Maryam Vosoughian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2595

Email address

maryam.vosoughian@mail.sbm.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of general anesthesia and spinal anesthesia on serum cytokines in cesarean section patients

Public title

The effect of type of anesthesia method on serum

cytokines in cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
All patients refer to Taleghani Hospital for cesarean section Patients who fill out the consent form ASA Class I, II patients
Exclusion criteria:
Patients with any coagulation disorder Patients with antiphospholipid syndrome

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants are randomly divided into study groups 1 or 2 using a random number table. The names of the assigned group are written on the cards and placed in numbered and sealed envelopes. When each eligible woman enters the study, a numbered envelope is opened in sequence and the group is assigned.

Blinding (investigator's opinion)
Single blinded

Blinding description
A person who is not involved in the study opens the numbered envelope in sequence. Laboratory staff and data analysts are also unaware of the assignment of groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Taleghani Hospital, Velenjac Ave., Yaman St., Arabi st., Tehran, Iran.
City

Tehran
Province
Tehran
Postal code
1985717443
Approval date
2019-05-14, 1398/02/24
Ethics committee reference number
IR.SBMU.MSP.REC.1398.169

Health conditions studied

1

Description of health condition studied
Serum cytokines level
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum cytokines level
Timepoint
Measurement of cytokines before cesarean section and half an hour after recovery
Method of measurement
ELIZA method

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:. In spinal anesthesia group, 2.8 cc of 0.5% Marcaine(Bupivacaine MYLAM SANT PRIEST-FRANCE) is injected into the L3-L4 or L4-L5 space.
Category
Treatment - Other

2

Description
Intervention group: . In the general anesthesia group, rapid sequence induction by thiopental 4-6 mg / kg and succinylcholine 1-1.5 mg / kg and endotracheal intubation is performed . Then oxygen and nitrous oxide 50% and 0.8% isoflurane is continued . After delivery of baby, fentanyl 200µgr per 70 kg is injected.
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Talegani Hospital

Full name of responsible person

Maryam Vosoughian

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Talegani Hospital, Velenjac Ave., Yaman St., Arabi st.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Dabbagh

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Talegani Hospital, Velenjac Ave., Yaman St., Arabi st.,
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alidabbagh@yahoo.com

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

30

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Vosoughian

Position

Associated Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

Maryam Vosoughian

Position

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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

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

The access period will start 8 months after the results are published.

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The use of the results for additional studies is allowed with the permission of the responsible author.

From where data/document is obtainable

Maryam Vosoughian Talegani Hospital, Velenjac Ave.,
Yaman St., Arabi st., Tehran, Iran

maryam.vosoghian@mail.sbm.ac.ir 0098 9121386084

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

Documents will be sent to the applicant no later than one month after contacting the author by e-mail.

Comments