Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

The effect of general anesthesia and spinal anesthesia on the procedure and complications of cesarean surgery in pregnant patients

Protocol summary

Study aim

In this study, the effects of general anesthesia or spinal anesthesia in pregnant mothers undergoing cesarean surgery will be measured on intraoperative bleeding, newborn Apgar score, blood pressure and pain in the first 24 hours after surgery, and the results between the two groups. will be compared.

Design

A parallel two-group clinical trial involving 60 patients

Settings and conduct

The present research will be conducted on patients undergoing caesarean section in Fatemieh Hospital, Hamadan, in 2023. In this study, there is no possibility of blinding and the study is conducted in an open-label manner. The researcher will visit the operating room department of Fatemieh Hospital in two shifts, morning and evening, and informed consent will be obtained from the patients. Then, after grouping the patients into two groups randomly, the desired variables will be measured.

Participants/Inclusion and exclusion criteria

Pregnant women undergoing caesarean section between 15 and 40 years of age, with no history of high blood pressure, no coagulopathy, their birth weight between 2.5 and 3.8 kg and a full-term baby who gave informed consent to participate in the study. have no history of stillbirth and do not currently have multiple births and do not need a pain pump. «نماد «مورد تأیید انجمن surgery

Intervention groups

Considering that most cesarean surgeries are performed using spinal anesthesia, therefore, we will consider the spinal anesthesia group as the control group and general anesthesia as the intervention group, and also the intended intervention, the allocation of general anesthesia during the beginning A cesarean section is considered.

Main outcome variables

Intraoperative bleeding rate, Apgar score at birth, average blood pressure in the first 24 hours after surgery, average pain level in the first 24 hours after

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230225057532N1**
Registration date: **2023-03-21, 1402/01/01**
Registration timing: **prospective**

Last update: **2023-03-21, 1402/01/01**
Update count: **0**

Registration date

2023-03-21, 1402/01/01

Registrant information

Name
serveh mohammadi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 44 4222 7846
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serveh.mohamadi76@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-03, 1402/01/14

Expected recruitment end date

2023-07-05, 1402/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of general anesthesia and spinal anesthesia on the procedure and complications of cesarean surgery in pregnant patients

Public title
A comparative study of the effect of general and spinal anesthesia on the complications and process of cesarean surgery in pregnant patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women between 15 and 40 years old No history of high blood pressure Absence of coagulation disorders The weight of the newborn baby is between 2.5 and 3.5 kg Full term baby Informed consent to participate in the study

Exclusion criteria:
History of stillbirth of the mother Patients in need of a pain pump Multiple births

Age
From **15 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Allocation of patients in two groups will be done in random blocks so that; The block size is equal to 4. The randomization tool in this research will be the use of four envelopes containing two sheets J and two sheets S, each time by removing one of the sheets, the patient will be placed in the general anesthesia or spinal anesthesia group. The removed sheets will not be returned to the envelope until the 4 sheets are finished. After determining the assignment of the first 4 patients, the sheets are returned to the envelope and the next 4 patients will continue in this way until the sample size is completed.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Hamadan University of Medical Sciences

Street address
4th Floor, Vice-Chancellor for Research and Technology, University Headquarters, Shahid Fahmideh Blvd.

City
Hamadan

Province
Hamadan

Postal code
6517838678

Approval date
2023-02-10, 1401/11/21

Ethics committee reference number
IR.UMSHA.REC.1401.1042

Health conditions studied

1

Description of health condition studied
Cesarean section

ICD-10 code
Z37.0

ICD-10 code description
Single live birth

Primary outcomes

1

Description
Bleeding rate

Timepoint
During surgery

Method of measurement
The digital scale is used to measure the amount of bleeding during the operation, so that at the end of the operation, gases contaminated with blood are placed on the digital scale and each gram of gas weight is considered equal to one cc of bleeding. Also, in this method, the amount of blood sucked in the suction device is also calculated, so that the amount of blood collected is announced based on the ratings of the tank of the suction device.

2

Description
Mother's average blood pressure

Timepoint
The first 24 hours after surgery (in the time intervals of entering the ward and 6, 12, 24 hours after entering the ward)

Method of measurement

The use of monitoring and manometer device is to measure the blood pressure of the patient in the first 24 hours, so that it will be measured and recorded at intervals of the moment of entering the ward and 6, 12, 24 hours after entering the ward.

3

Description
Apgar score of the baby
Timepoint
When the baby is born
Method of measurement
Apgar scale is used to check the effects of anesthesia on the baby

4

Description
Average amount of maternal pain
Timepoint
The first 24 hours after surgery (between the moment of entering the ward and twelve hours and twenty-four hours after entering the ward)
Method of measurement
The NRS criterion is used. In this method, a person rates their pain using a scale of zero to ten.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this intervention study, the allocation of general anesthesia during the beginning of cesarean surgery is considered.
Category
Prevention

2

Description
Control group: In this study, spinal anesthesia is routinely used for the control group.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemiyeh hospital
Full name of responsible person
Serveh Mohamadi
Street address
Pasdaran Street
City
Hamadan
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Hamadan
Postal code
6517997178
Phone
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Email
h-fatemiyeh@umsha.ac.ir
Web page address
http://fth.umsha.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Reza Shokohi
Street address
Shahid Fahmideh Street
City
Hamadan
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Postal code
6517838736
Phone
+98 81 3131 0000
Email
vc_research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hmadan univercity 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
Hamedan University of Medical Sciences
Full name of responsible person
Serveh Mohammadi
Position
Student
Latest degree

Master

Other areas of specialty/work

Surgical Tecnologie

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Person responsible for updating data

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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