Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparison the effect of serum therapy(Ringer,D/S&HES) before spinal anesthesia in elective cesarean section on patients' hemodynamic

Protocol summary

Summary

Low blood pressure during spinal anesthesia is generally can cause significant mortality and morbidity . This study aimed to investigate the effects of changes in BP, HR and MAP and SPO2 under spinal anesthesia for cesarean section is designed in pregnant women. Random, double-blind study designed after approval by the university ethics committee to refer all pregnant women for elective cesarean section and are part of the inclusion criteria offering fully explained consent form and the trial is conducted and from them satisfaction. In this study, 90 women with normal pregnancy 40-20 years with ASA class 1 and 2 and a height of 160-180 cm are now. The main condition exclusion is neurological disease, neuromuscular disorder, cardiovascular disease, high blood pressure, diabetes, organ failure, drug use, blood coagulation disorders, pre-eclampsia and eclampsia. Interventions,is the injection of 10 ml per kilogram of body weight of the serum before spinal anesthesia (only medication is the sugar-salt or hydroxi ethyl starch 6% or ringer only once.). Study done in 1395. Primary outcomes are included blood pressure and heart rate and blood oxygen saturation arteries. No secondary outcome . 1-Objectives: Compare the average heart rate and blood pressure, serum therapy with Dexterossalin" Ringer" and Hydroxi ethyl starch before spinal anesthesia in patients undergoing elective cesarean section at the time of measurement. 2-Design: Nine randomized blocks in which three cards to each group's efficiency in Block Nine 3-way to do: The study is double-blind random after serum injection to the patient under spinal anesthesia and vital signs were recorded. 4-Participants including major eligibility criteria: - Terms of Inclusion: women twenty to forty years of "normal Pregnancy" with ASA class 1 and 2 "height 160-180 centimeters -Terms of Exclusion: neurological disease "neuromuscular" heart disease "hypertension" diabetes "organ failure" drug abuse" coagulation disorders" eclampsia and preeclampsia. 5-Intervention: 10 ml per kilogram of body weight injection of the serum before spinal anesthesia. Then measure the blood pressure and heart rate every 10 minutes to 2 hours. There is no control group.(Ringer only medication or a sugar-salt or hydroxi ethyl starch is 6% and only once.) 6-Main outcome measures variables: does not have 7-primary variables: blood pressure, mean arterial pressure, heart rate. 8- percentage of oxygen in arterial blood.

General information

Acronym

with out acronym

IRCT registration information

IRCT registration number: **IRCT2016110730770N1**
Registration date: **2017-03-18, 1395/12/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-03-18, 1395/12/28

Registrant information

Name

Ahmad ali Khademi

Name of organization / entity

Zahedan university of medical sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancello forresearch,Zahedan university of Medical Sciences

Expected recruitment start date
2017-01-19, 1395/10/30
Expected recruitment end date
2017-05-22, 1396/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of serum therapy(Ringer,D/S&HES) before spinal anesthesia in elective cesarean section on patients' hemodynamic

Public title
Comparison the effect of serum therapy(Ringer,D/S&HES) before spinal anesthesia in elective cesarean section on patients' hemodynamic
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Twenty to forty years with normal pregnancy؛ with ASA class 1 and 2؛ with a height of 160-180 cm Exclusion criteria: neuromuscular disorders؛ and neurological diseases؛ heart disease؛ high blood pressure؛ diabetes؛ organ failure؛ drug abuse؛ coagulation disorders؛ BMI more than 30 before pregnancy" and pre-eclampsia or eclampsia.
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
2. The study population (inclusion and exclusion criteria are listed): The study population consisted of all mothers pregnant first parity cesarean elective surgery during 1395 in Imam Ali hospital and placed under spinal anesthesia.

Secondary Ids

1

Registry name
does not have
Secondary trial Id
does not have
Registration date
empty

2

Registry name
ندارد
Secondary trial Id
ندارد
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Zahedan University of Medical Sciences
Street address
Zahedan university of medical sciences، Janat pardis Blvd، DR، Hesabi square، Daneshgah Street
City
Zahedan
Postal code
9816743463
Approval date
2016-01-29, 1394/11/09
Ethics committee reference number
IR.ZAUMS.REC.1394.28

Health conditions studied

1

Description of health condition studied
Effects of intravenous therapy with D/S’ringer or hydroxi ethyl starch in spinal anesthesia for elective cesarean section on patient’s hemodynamic
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Saturation Pressure of arterial oxygen
Timepoint
Every 10 minutes to two hours
Method of measurement
Is performed by anesthesia machine

2

Description
Blood pressure, heart rate-MAP-spo2
Timepoint

Every 10 minutes to two hours.

Method of measurement

All is done by anesthesia machine

3

Description

Heart rate

Timepoint

Every 10 minutes to two hours

Method of measurement

Is performed by anesthesia machine

4

Description

Mean arterial pressure

Timepoint

Every 10 minutes to two hours

Method of measurement

Is performed by anesthesia machine

Secondary outcomes

1

Description

No variable

Timepoint

does not have

Method of measurement

does not have

Intervention groups

1

Description

Random, double-blind study designed and After approval by the university ethics committee and recorded in clinical studies in the Iranian system Refer to all pregnant women for elective cesarean section and are part of the inclusion criteria Offering fully explained consent form and the trial is conducted and from them satisfaction. In this study, 90 women with normal pregnancy 40-20 years with ASA class 1 and 2 and a height of 160-180 cm are now. This clinical trial, in which each group of 30 selected and matched undertaking uncomplicated elective cesarean section after informed consent of the patients in this study are. This is a double-blind study, the researcher is a person who collects information relevant group are totally unaware. After a full explanation and written informed consent from the patient eligible patients will be enrolled in the study. And the timely arrival of the patient to the operating room the patient's Put a wedge under the right side of the patient to prevent pressure on the lower venacava. The standard monitoring, including ECG (electrocardiogram) and NIBP (Non-Invasive Blood Pressure) and HR (heart rate) and SPo2 (percentage of oxygen in arterial blood) are placed. The patient is placed in the supine on a bed operating room and placed in such a way that the right hip 15-degree wedge up. Vital signs include BP-HR-MAP is assorted LoginRegister. Serum interest at a rate of 10cc/kg. injected into 15 to 30 minutes. Vital signs (HR-MAP-BP) is recorded. Then the patient in the sitting position after preb with bethadine; space L3-L4 or L4-L5 using 12/5 mg of bupivacaine 0/5% plus 25 micrograms fentanyl with needle number Gage24 or 25 Gage (needle type is Quincke) under spinal anesthesia by a person qualified or project is. (If the number of attempts for spinal anesthesia (injection) is more than 3 times patient out of the study). The patient is placed supine position immediately. Vital signs are recorded immediately. This operation is repeated for 2 hours every 2 minutes to 15 minutes, then every 10 minutes until the end of the second hour trademarks. In the period after spinal anesthesia if the systolic blood pressure lower than 100 mm Hg or 25% compared to the initial pressure drop immediately treated with ephedrine 5 mg IV start until the patient's blood pressure is higher than 100 mm Hg reach every 2 minutes, repeat. Three times after treatment begins with ephedrine treatment with epinephrine. Interventions,is the injection of 10 ml per kilogram of body weight of the serum before spinal anesthesia (only medication is the sugar-salt or hydroxi ethyl starch 6% or ringer only once.). There is no control group.

Category

N/A

2

Description

The first intervention: an injection of 10 cc of Dexteros-salin serum per kg of body weight before spinal anesthesia (only once) for 15 minutes. Then measure the blood pressure numbers mean arterial blood pressure and heart rate, arterial blood oxygen saturation by anesthesia machine. Measuring is every 2 minutes to 15 minutes, then every 10 minutes until 2 hours after the onset of spinal anesthesia .no control group .

Category

N/A

3

Description

Second intervention: an injection of 10 cc of Ringer per kg of body weight before spinal anesthesia (only once) for 15 minutes. Then measure the blood pressure numbers mean arterial blood pressure and heart rate, arterial blood oxygen saturation by anesthesia machine. Measuring is every 2 minutes to 15 minutes, then every 10 minutes until 2 hours after the onset of spinal anesthesia .no control group .

Category

N/A

4

Description

Third intervention:an injection of 10 cc of Hydroxi ethil estarch 6% per kg of body weight before spinal anesthesia (only once) for 15 minutes. Then measure the

blood pressure numbers mean arterial blood pressure and heart rate, arterial blood oxygen saturation by anesthesia machine. Measuring is every 2 minutes to 15 minutes, then every 10 minutes until 2 hours after the onset of spinal anesthesia .no control group .

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

DR. Khademi. Ahmad Ali

Street address

Imam Ali Hospital، Salamat Boulevard، KHalije Fars Highway

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancello forresearch, Zahedan university of Medical Sciences

Full name of responsible person

Rafigh doost، Hooshang

Street address

Zahedan university of medical sciences، Janat pardis Blvd، DR، Hesabi square، Daneshgah Street

City

Zahedan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancello forresearch, Zahedan university of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan university of Medical sciences

Full name of responsible person

DR. Birami. Faranak

Position

Specialized doctor anesthesia/ Assistant Professor

Other areas of specialty/work

Street address

Zahedan university of medical sciences، Janat pardis Blvd، DR، Hesabi square، Daneshgah Street

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Full name of responsible person

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Other areas of specialty/work

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Full name of responsible person

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Position

Specialized doctor anesthesia/ Assistant Professor

Other areas of specialty/work

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Email
public@zaums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty