Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The evaluation of the effect of intravenous dexamethasone on hemodynamic variables and post-spinal hypotension in the women undergoing cesarean section

Protocol summary

Study aim
Determining the effect of intravenous dexamethasone on hemodynamic variables and the rate of hypotension after spinal anesthesia in women undergoing cesarean section

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 is performed on 60 patients. Random allocation software version 1.0 is used for randomization under Windows.

Settings and conduct
This study is performed on women candidates for cesarean section under spinal anesthesia in Kosar operating room of Shahid Sadoughi Hospital in Yazd. Prior to spinal anesthesia, the study drug or placebo is injected intravenously and then hemodynamic variables are measured and recorded during surgery and during recovery. This study is double-blind and neither the researcher nor the patient knows the type of drug prescribed, so that the drugs are prepared and coded in two identical syringes and the third person injects the drug for the patient based on the specified code.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women aged 20-35 years, Class I ASA, non-emergency cesarean section, spinal anesthesia Non-inclusion criteria: dissatisfaction with the study, diabetes, preeclampsia and eclampsia, BMI above 35 and below 18, severe heart, lung, kidney and liver disease, drug and psychiatric addiction, and cases of emergency cesarean section

Intervention groups
Intervention group: In this group, 30 patients were randomly injected with 8 mg dexamethasone (equivalent to 2 ml) slowly intravenously before spinal anesthesia. Control group: 30 patients were randomly injected with 2 ml of normal saline slowly intravenously before spinal anesthesia

Main outcome variables
Systolic blood pressure; diastolic blood pressure; mean arterial blood pressure; heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100102002963N34**
Registration date: **2022-01-23, 1400/11/03**
Registration timing: **prospective**

Last update: **2022-01-23, 1400/11/03**
Update count: **0**

Registration date
2022-01-23, 1400/11/03

Registrant information

Name
Shekoufeh Behdad

Name of organization / entity
Shahid Sadoughi University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 35 1822 1386

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2022-09-06, 1401/06/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The evaluation of the effect of intravenous dexamethasone on hemodynamic variables and post-spinal hypotension in the women undergoing cesarean section

Public title
The evaluation of the effect of administration of dexamethasone on hemodynamic variables and hypotension due to regional anesthesia in the women undergoing cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
20-35 years old women with term pregnancy American Society of Anesthesia (ASA) physical status I non-emergency repeated cesarean delivery spinal anesthesia
Exclusion criteria:
BMI>35 chronic hypertension placenta previa placenta acreta gestational age <28 weeks Polyhydramnios
Age
From **20 years** old to **35 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomly allocate 60 eligible applicants, we randomly divide them into two groups of 30 people. For this purpose, we use Random allocation software version 1.0 under Windows to create a sequence, and by using this software we make A list which is specified from 1 to 60 with group A or B treatment By Using this list, we give the first person who is eligible to enter the study, number one and the last person the number 60, then based on the random allocation list and by the software, it is determined which group A or B each person is in. Each drug is placed in a package and the packages are coded and based on the table of random numbers and specified code, the drug is given to patients by a third person who is not involved in evaluating patients and recording results.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and researchers themselves are unaware of which medication the patient has received, in this way, each drug is placed in a package and the packages are coded and based on the table of random numbers and specified code, the drug is given to patients by a third person who is not involved in evaluating patients and recording results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Medical School - Shahid Sadoughi University of Medical Sciences, Yazd
Street address
Faculty of Medicine. Shohadayegomnam Blv.Yazd
City
Yazd
Province
Yazd
Postal code
8915887857
Approval date
2021-10-27, 1400/08/05
Ethics committee reference number
IR.SSU.MEDICINE.REC.1400.262

Health conditions studied

1

Description of health condition studied
Hemodynamic variables and hypotension after spinal anesthesia in the women undergoing cesarean section
ICD-10 code
I95.81
ICD-10 code description
Postprocedural hypotension

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes during recovery
Method of measurement
Using monitoring device

2

Description
Diastolic Blood Pressure
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes during recovery
Method of measurement
Using monitoring device

3

Description
Mean Arterial Pressure
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes during recovery
Method of measurement
Using monitoring device

4

Description
Heart Rate
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes during recovery
Method of measurement
Using monitoring device

5

Description
Drop in systolic blood pressure below 90 mm Hg
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes during recovery
Method of measurement
Using monitoring device

Secondary outcomes

1

Description
Bradycardia(drop in heart rate below 50/ min)
Timepoint
Before the injection of the study drug, immediately after the spinal anesthesia and then every three minutes until the birth of the baby and then every 5 minutes until the end of surgery, and every 15 minutes during recovery
Method of measurement
Using monitoring device

2

Description
hyperglycemia(blood glucose more than 200mg/dl)
Timepoint
In the recovery (one hour after operation)
Method of measurement
using Glucometer

Intervention groups

1

Description
Intervention group: In this group, dexamethasone at a dose of eight mg equivalent to 2 ml is injected slow intravenously and once immediately before spinal anesthesia to eligible patients.
Category
Treatment - Drugs

2

Description
Control group: In this group, 2 ml normal saline is injected slow intravenously and once immediately before spinal anesthesia to eligible patients.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Dr Shekoufeh Behdad
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Shahid Sadoughi Hospital, Ebnesina Blv, Safayieh, Yazd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr Amirhooshang Mehrparvar

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Central building of Yazd University of Medical Sciences, Bahonar Square
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Dr Shekoufeh Behdad
Position
Faculty member and full professor of Shahid Sadoughi University of Medical Sciences, Yazd
Latest degree
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Other areas of specialty/work
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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