Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of Dexamethasone and Methylergonovine injection in preventing headache after spinal anesthesia in Cesarean Section

Protocol summary

Study aim

Comparison of Dexamethasone and Metergine intravenous Injection in prevention of headache after spinal anesthesia in Cesarean Section.

Design

One hundred patients are entered into a double-blind, phase 2-3 clinical trial and they are randomly assigned into two intervention 1 (Dexamethason) or intervention 2 (Methergine) groups.

Settings and conduct

Patients at Fatemiye Hospital of Hamadan undergo cesarean section by spinal anesthesia and after birth of the baby, randomly receive one of two Dexamethasone and Methergine administered by an anesthetist nurse with the same volume and shape.So that, the patient and anesthetist (evaluator)do not know the kind of medication prescribed. Patients are then tested in terms of headaches during and a week after surgery.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 18 to 45 ; candidate for cesarean section under spinal anesthesia; ASA Class 1 and 2. Non Inclusion Criteria: History of migraine headache; Sinusitis ; Heart disease; Eclampsia and preeclampsia; Liver and kidney failure; corticosteroid use; Diabetes; Raynoode Phenomen; Spinal anesthesia contraindications; Patients who undergo general anesthesia.

Intervention groups

In intervention group 1 (group A): After baby birth and clamp of the umbilical cord, Dexamethasone is injected by anesthesiologist intravenously and patients are examined for headache during and one week after surgery. In intervention group 2 (group B): After baby birth and clamp of the umbilical cord, Methergine is injected by anesthesiologist intravenously and patients are examined for headache during and one week after surgery.

Main outcome variables

Systolic blood pressure; Diastolic blood pressure; mean arterial pressure (MAP); Heart rate; SPO2 ; Nausea and vomiting; Dizziness; Tinnitus; Epigastric pain; Headache during surgery; Headache in 24 hours and one week after surgery .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N11**
Registration date: **2019-01-11, 1397/10/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-11, 1397/10/21**
Update count: **0**

Registration date

2019-01-11, 1397/10/21

Registrant information

Name
Nahid Manuchehrian
Name of organization / entity
Hamedan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-01, 1397/04/10

Expected recruitment end date
2019-03-21, 1398/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Dexamethasone and Methylergonovine injection in preventing headache after spinal anesthesia in Cesarean Section

Public title
Comparison of two drugs in the prevention ofheadache after spinal anaestesia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 45 years old candidates for cesarean section under spinal anesthesia Physical ASA Class 1 and 2
Exclusion criteria:
Patients with a history of migraine headache Sinusitis Heart disease Hypertension Eclampsia and pre-eclampsia Liver and kidney failure History of corticosteroid use Diabetes Raynoode Phenomen Spinal anesthesia contraindications (dissatisfaction, increased intracranial pressure, local infection, coagulopathy, anemia, hypovolemia, etc.) Patients who do not have the necessary co-operation in answering questions Those who are reluctant to continue to participate in the study Patients who have failed spinal anesthesia and undergo general anesthesia
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study , a randomized block design with four replications is used. we provide four sheets of paper. we write two letters A and on two other sheets of letter B. We mix the papers together and put them in the drawer of the table.With each of the qualified patients, one of the papers is taken out randomly and will be assigned to one of the two Dexamethasone or Methyl ergonovine groups, depending on whether the drawn sheet is either A or B. After the random drawn out of four sheets, all the papers will be returned to the drawer and again the above procedure will continue for the next four patients until it reaches the sample volume.
Blinding (investigator's opinion)
Double blinded
Blinding description
After birth of the baby and the clamp of the umbilical cord, one of the two drugs, Dexamethasone and Methylergonovine, is prepared by the anesthetist nurse (who knows nothing about the plan), in syringes of the same volume and shape, and is administered intravenously and slowly to each patient in two groups A or B by an anesthetist. Thus, the patient, the anesthetist (evaluator) and the analyzer are not aware of any prescriptive substance.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hamadan University of Medical Sciences
Street address
Mahdie Street
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Hamadan
Province
Hamadan
Postal code
6517838678
Approval date
2018-06-30, 1397/04/09
Ethics committee reference number
IR.UMSHA.REC.1397.221

Health conditions studied

1

Description of health condition studied
Post dural puncture headache
ICD-10 code
O74.5
ICD-10 code description
Spinal and epidural anaesthesia-induced headache during labour and delivery

Primary outcomes

1

Description
Frequency of headache
Timepoint
During the surgery, the first 24 hours after surgery and one week after surgery
Method of measurement
Ask the patient

2

Description
Headache time
Timepoint
During the surgery, the first 24 hours after surgery and one week after surgery
Method of measurement
Ask the patient

3

Description
Headache severity
Timepoint
During the surgery, the first 24 hours after surgery and one week after surgery
Method of measurement
VAS of pain

4

Description
Duration of the headache
Timepoint
During the surgery, the first 24 hours after surgery and one week after surgery
Method of measurement
Ask the patient

Secondary outcomes

1

Description
nausea and vomiting
Timepoint
During the surgery
Method of measurement
Observation and ask the patient

2

Description
Heart Rate
Timepoint
Every two minutes for 10 minutes and then every 10 minutes to 60 minutes
Method of measurement
Pulse oximetry device

3

Description
Percentage of arterial oxygen saturation
Timepoint
Every two minutes for 10 minutes and then every 10 minutes to 60 minutes
Method of measurement
Pulse oximetry device

4

Description
Dizziness
Timepoint
During the surgery
Method of measurement
ask the patient

5

Description
Epigastric Pain
Timepoint
During the surgery
Method of measurement
ask the patient

6

Description
Tinnitus
Timepoint
During the surgery
Method of measurement
ask the patient

7

Description
Systolic Blood Pressure
Timepoint
Every two minutes for 10 minutes and then every 10 minutes to 60 minutes
Method of measurement
Non-invasive automatic barometric device

8

Description
Diastolic Blood Pressure
Timepoint
Every two minutes for 10 minutes and then every 10 minutes to 60 minutes
Method of measurement
Non-invasive automatic barometric device

9

Description
Mean Arterial Pressure
Timepoint
Every two minutes for 10 minutes and then every 10 minutes to 60 minutes

Method of measurement
Non-invasive automatic barometric device

Intervention groups

1

Description
First Intervention group: After the birth of the baby and the clamp of the umbilical cord, a single dose of 8 mg dexamethasone phosphate (2ml), produced by the Caspian Company and prepared by an anesthetic nurse in in a bottle with same volume and shape (2ml) to the other group, is injected by an anesthesiologist intravenously and slowly.
Category
Prevention

2

Description
Second Intervention group: After the birth of the baby and the clamp of the umbilical cord, a single dose of 0.2 mg(1ml) Methergine (Methylergonovine maleate), produced by the Minoo Company and Prepared by an anesthetic nurse in a bottle with same volume and shape (2 ml) to the other group, is injected by an anesthesiologist intravenously and slowly
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Hamedan 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
Hamedan University of Medical Sciences
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Nahid Manouchehrian
Position
Associate Professor of Hamadan University of Medical Sciences
Latest degree
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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