Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing intravenous hydrocortisone versus ketamine on reducing of post spinal shivering in cesarean section

Protocol summary

Summary

In this prospective double blind clinical trial, 150 pregnant women aged 18-40 years old with ASA class 1&2 candidates for cesarean section under spinal anesthesia in Fatemie Hospital are randomly divided into three groups in 5 random block. Exclusion criteria: high risk pregnancy; multiple pregnancy; emergency cesarean section; pre-eclampsia & eclampsia; cardiovascular disease; respiratory disease; psychiatric disease; thyroid disease; diabetes melitus; long history of corticosteroids administration; hypertension; peptic ulcer; need to get blood products; temperature >38 c and contraindication of spinal anesthesia. After spinal anesthesia and neonate delivery patients received 3cc hydrocortisone (2 mg/kg, "A" group) or 3cc ketamine (0.5 mg/kg, "B" group) or 3cc normal saline (%0.9, "C" group) intravenously in 10-15 S duration after umbilical cord clamping. In all patients systolic and diastolic pressure, mean arterial pressure, heart rate, oxygen saturation level, body temperature and sedation score were recorded before anesthesia and then every minute for 5 minute, every 5 minutes for 15 minute, every 10 minutes until the end of surgery. Also, hallucination, nausea and vomiting, incidence and intensity of shivering and using amount of pethidine and ephedrine were recorded in questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016073110841N6**
Registration date: **2016-09-14, 1395/06/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-09-14, 1395/06/24

Registrant information

Name
Nahid Manuchehrian
Name of organization / entity
Hamedan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 81 1827 7012
Email address
manouchehrian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences, vice chanceller for research

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing intravenous hydrocortisone versus ketamine on reducing of post spinal shivering in cesarean section

Public title

Prevention of post spinal shivering by drugs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women aged 18 -40 years old; ASA class 1&2; term pregnant patients (gestational

age 36-40 weeks) and candidate for cesarean section under spinal anesthesia . Exclusion criteria: high risk pregnancy; multiple pregnancy; emergency cesarean section; pre-eclampsia & eclampsia; cardiovascular disease; respiratory disease; psychiatric disease; thyroid disease; diabetes melitus; long history of corticosteroids administration; hypertension; peptic ulcer; need to get blood products; temperature >38 c and contraindication of spinal anesthesia.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan university of Medical Sciences

Street address
Fahmide Street

City
Hamadan

Postal code
6517838678

Approval date
2015-06-23, 1394/04/02

Ethics committee reference number
IR.UMSHA.REC.1394.462

Health conditions studied

1

Description of health condition studied
post spinal shivering

ICD-10 code
O74.9

ICD-10 code description
Complication of anaesthesia during labour and delivery, unspecified

Primary outcomes

1

Description
systolic and diastolic blood presure

Timepoint
1-2-3-4-5-10-15-20-30-40-50-60 minutes after spinal anesthesia and 10-20 &30 minutes after arriving to recovery

Method of measurement
mmHg and by noninvasive automatic blood pressure monitoring

2

Description
Mean arterial pressure

Timepoint
1-2-3-4-5-10-15-20-30-40-50-60 minutes after spinal anesthesia and 10-20 &30 minutes after arriving to recovery

Method of measurement
mmHg and by noninvasive automatic blood pressure monitoring

3

Description
Heart Rate

Timepoint
1-2-3-4-5-10-15-20-30-40-50-60 minutes after spinal anesthesia and 10-20 &30 minutes after arriving to recovery

Method of measurement
Beat per minute and by ECG monitoring

4

Description
SPO2

Timepoint
1-2-3-4-5-10-15-20-30-40-50-60 minutes after spinal anesthesia and 10-20 &30 minutes after arriving to recovery

Method of measurement
Percent and by pulse oxymetry

5

Description
Tempreture

Timepoint
each 15 minutes until end of recovery

Method of measurement
degree and by medical oral termometer

6

Description
frequency of shivering
Timepoint
during sergury and in recovery
Method of measurement
Observation

7

Description
shiverig grading
Timepoint
during sergury and in recovery
Method of measurement
shivering score

8

Description
consumption of pethidine
Timepoint
during sergury and in recovery
Method of measurement
mg and by observation

9

Description
consumption ofephedrine
Timepoint
during sergury and in recovery
Method of measurement
mg and by observation

10

Description
Neonate APGAR
Timepoint
1&5 minutes after birth
Method of measurement
APGAR Score

Secondary outcomes

1

Description
sedation score
Timepoint
1-2-3-4-5-10-15-20-30-40-50-60 minutes after spinal anesthesia and 10-20 &30 minutes after arriving to recovery
Method of measurement
Ramsay score

2

Description
Hallocination
Timepoint
during surgery & recovery
Method of measurement
observation & interview

3

Description
nausea & vomiting
Timepoint
during surgery
Method of measurement
observation & interview

4

Description
nistagmus
Timepoint
during surgery & recovery
Method of measurement
Observation & Examination

Intervention groups

1

Description
After spinal anesthesia, in group A 2mg/kg hydrocortison (3ml),after clamping of umblical cord intravenously is injected.
Category
Prevention

2

Description
After spinal anesthesia , in ketamine group ,0.5 mg/kg ketamine (3ml) after clamping of umblical cord intravenously is injected .
Category
Prevention

3

Description
After spinal anesthesia, in control group 3ml normal salin , after clamping of umblical cord intravenously is injected.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Nahid Manouchehrian
Street address
Pasdaran Street

City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan University of Medical Sciences, vice chancellor for research
Full name of responsible person
Dr. Saeed Bashirian
Street address
Fahmide Street
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan University of Medical Sciences, vice chancellor for research
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
Hamadan University of Medical Sciences, Fatemie Hospital
Full name of responsible person
Nahid Manouchehrian
Position
Associated professor of anesthesia Department, Special Board of Anesthesia
Other areas of specialty/work
Street address
Pasdaran Street
City
Hamadan
Postal code
6517789971
Phone
+98 81 3827 7012
Fax
+98 81 3828 3939
Email
manuchehriann@gmail.com; manouchehrian@umsha.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamadan University of Medical Sciences, Fatemie Hospital
Full name of responsible person
Nahid Manouchehrian
Position
Associated professor of Anesthesia Department-Special Board of Anesthesia
Other areas of specialty/work
Street address
Pasdaran Street
City
Hamadan
Postal code
65177-89971
Phone
+98 81 3827 7012
Fax
+98 81 3828 3939
Email
manuchehriann@gmail.com; manouchehrian@umsha.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Hamadan University of Medical Sciences, Fatemie Hospital
Full name of responsible person
Nahid Manouchehrian
Position
Associated professor of Anesthesia Department-Special Board of Anesthesia
Other areas of specialty/work
Street address
Pasdaran Street
City
Hamadan
Postal code
65177-89971
Phone
+98 81 3827 7012
Fax
+98 81 3821 0171
Email
manuchehriann@gmail.com; manouchehrian@umsha.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