Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of subcutaneous ketamine infiltration on postoperative pain in elective cesarean section under spinal anesthesia.

Protocol summary

Summary

This is randomized double blind clinical trial (phase 2) with placebo that is done in 60 parturient 15 -45 years with ASA class 1&2 candidate for cesarean section under spinal anesthesia. Patients with history of hypertension; hyperthyroidism; convulsion; symptoms of increasing ICP; psychiatric disorders; ischemic heart disease; valvular heart disease; Ketamin allergy; liver & renal failure; alcohol or drugs abuse; spinal anesthesia contraindications(patients refuse, coagulation disorders, local infections, neurologic disorders, severe anemia,...); spinal failure & general anesthesia is excluded. In all patients after receiving 500 ml serum ringer and spinal anesthesia with 12.5 mg Bupivacain 0.5% cesarean section is done. After closure perituine in K group 0.5mg/kg(0.05ml/kg) ketamin and in P group (0.05ml/kg) normal saline subcutaneously is infiltrated.VAS of pain, BP, PR, RR & SPO2 in pre administration of drug , arrival to recovery , 30 minutes after staying in recovery, delivery time of recovery and 2, 4, 6, 8, 12 and 24 hours after surgery by nursing is measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031710841N4**
Registration date: **2013-04-22, 1392/02/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-04-22, 1392/02/02

Registrant information

Name

Nahid Manuchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Hamadan University Of Medical Sciences

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-09-22, 1392/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of subcutaneous ketamine infiltration on postoperative pain in elective cesarean section under spinal anesthesia.

Public title

Ketamin on reducing postoperative pain in cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between15-45 years old;ASA class 1&2; parturition candidate for cesarean section under spinal anesthesia. Exclusion criteria: history of hypertension; hyperthyroidism; convulsion; symptoms of increasing ICP ; psychiatric disorders; ischemic heart disease; valvular heart disease; allergy to Ketamin; liver

& renal failure; alcohol or drugs abuse; spinal anesthesia contraindications(patients refuse, coagulation disorders, local infections, neurologic disorders, sever anemia,...) ; spinal failure & general anesthesia for surgery.

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Hamadan University Of Medical Sciences,Medical School,Fahmide Street

City
Hamadan

Postal code
65178

Approval date
2012-11-22, 1391/09/02

Ethics committee reference number
3041/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied
cesarean postoperative pain

ICD-10 code
089.9

ICD-10 code description
Complication of anaesthesia during the puerperium, unspecified

Primary outcomes

1

Description
Diastolic Blood Pressure

Timepoint
before drug adminstration; arrive to recovery; 30 minutes after stay in recovery;exit from recovery; 2, 4, 6, 8, 12 & 24 hours after sergury.

Method of measurement
Non invasive Blood Pressure Monitoring

2

Description
Pain score

Timepoint
before drug adminstration; arrive to recovery; 30 minutes after stay in recovery;exit from recovery; 2, 4, 6, 8, 12 & 24 hours after sergury.

Method of measurement
10 centimeter ruller

3

Description
Systolic Blood Pressure

Timepoint
before drug adminstration; arrive to recovery; 30 minutes after stay in recovery;exit from recovery; 2, 4, 6, 8, 12 & 24 hours after sergury.

Method of measurement
Non invasive Blood Pressure Monitoring

4

Description
Heart rate

Timepoint
before drug adminstration; arrive to recovery; 30 minutes after stay in recovery;exit from recovery; 2, 4, 6, 8, 12 & 24 hours after sergury.

Method of measurement
Non invasive Blood Pressure Monitoring

5

Description
Respiratory rate

Timepoint
before drug adminstration; arrive to recovery; 30 minutes after stay in recovery;exit from recovery; 2, 4, 6, 8, 12 & 24 hours after sergury.

Method of measurement
Observation & Examination

6

Description
Blood oxygenation

Timepoint
before drug adminstration; arrive to recovery; 30

minutes after stay in recovery;exit from recovery; 2, 4, 6, 8, 12 & 24 hours after sergury.

Method of measurement

Non invasive Blood Pressure Monitoring

7

Description

Analgesic requirement in 24 hours

Timepoint

During 24 hours

Method of measurement

Observation & calculation

Secondary outcomes

1

Description

Nausea

Timepoint

Preadminstration, arrive to recovery, 30 minutes after stay in recovery,exit of recovery, 2- 4- 6- 8- 12 & 24 hours after sergury

Method of measurement

Observation

2

Description

Hallosination

Timepoint

Preadminstration, arrive to recovery, 30 minutes after stay in recovery,exit of recovery, 2- 4- 6- 8- 12 & 24 hours after sergury

Method of measurement

Observation &Examination

3

Description

Nistagmus

Timepoint

Preadminstration, arrive to recovery, 30 minutes after stay in recovery,exit of recovery, 2- 4- 6- 8- 12 & 24 hours after sergury

Method of measurement

Observation &Examination

4

Description

Sedation Level

Timepoint

pPreadminstration, arrive to recovery, 30 minutes after stay in recovery,exit of recovery, 2- 4- 6- 8- 12 & 24 hours after sergury

Method of measurement

Ramsay Scale

5

Description

Vomiting

Timepoint

Preadminstration, arrive to recovery, 30 minutes after stay in recovery,exit of recovery, 2- 4- 6- 8- 12 & 24 hours after sergury

Method of measurement

Observation

Intervention groups

1

Description

After closure perituine in K group 0.5mg/kg(0.05ml/kg) ketamin subcutaneously is infiltrated and patient is transferd to recovery room.

Category

Prevention

2

Description

After closure perituine in P group (0.05ml/kg) normal salin subcutaneously is infiltrated and patient is transfered to recovery room.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nahid Manouchehrian

Street address

Fatemieh Hospital ,Pasdaran Street

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University Of Medical Science ,Vice chancellor for research

Full name of responsible person

Dr. Heidar Tavilany

Street address

Hamadan University Of Medical Science,Medical School,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 Science ,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
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Hamadan University of Medical Science
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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