

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The investigation of hemodynamic effects of intravenous Ketamine after spinal anaesthesia for caesarean section

Protocol summary

Summary

Ketamine is a safe and inexpensive drug and clinical experience shows that intravenous Ketamine can prevent intraoperative hypotension and stress and induce longer postoperative analgesia. In this study, we compared the hemodynamic and analgesic effects of low dose intravenous Ketamine + Midazolam and intravenous Midazolam alone, was given immediately after spinal anesthesia. 60 individuals aged 18 years and over with ASA (American Society for Anesthesiology) Class 1 or 2, were randomly assigned into two groups. Arterial pressures, heart rate values, adverse effects, the time of first request for postoperative analgesia, visual analogue pain scores, total analgesic consumptions at 24 h were recorded in all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101293468N4**

Registration date: **2011-04-04, 1390/01/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-04, 1390/01/15

Registrant information

Name

Mohammad Reza Hajiesmaeili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences and Health Services

Expected recruitment start date

2010-04-21, 1389/02/01

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation of hemodynamic effects of intravenous Ketamine after spinal anaesthesia for caesarean section

Public title

The investigation of hemodynamic effects of intravenous Ketamine after spinal anaesthesia for caesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1- ASA=1,2; 2- No hx of recent head trauma; 3- NO hx of opium addiction; 4- NO hx of psychiatric drug consumption; 5- NO hx of hallucination; 6- NO hx of delirium; 7- NO hx of hypertension; 8- NO hx of ischemic heart disease; 9-NO hx of known hypersensitivity to study drug; 10- Elective cesarean; 11- age above 18 years. Exclusion criteria: 1- hypersensitivity to study drug; 2- need to additive dose of Ketamine; 3- unexpected event during surgery.

Age

From **18 years** old

Gender

Female

Phase

2-3

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

Vice chancellor for research, Shahid Sadoughi
University of Medical Sciences and Health Services,

Street address

Shahid Sadoughi University of Medical Sciences and
Health Services

City

Yazd

Postal code

Approval date

2009-08-20, 1388/05/29

Ethics committee reference number

1194

Health conditions studied

1

Description of health condition studied

anesthesia for cesarean delivery

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

hemodynamic variable

Timepoint

2 minute

Method of measurement

non invasive hemodynamic monitoring

Secondary outcomes

1

Description

post operative pain

Timepoint

1 hour

Method of measurement

VAS

Intervention groups

1

Description

Intervention group: Ketamine 30 milligram + 1 milligram
midazolam = 2 milliliter intravenously

Category

Prevention

2

Description

Control group: 1 milligram midazolam = 2 CC

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi hospital

Full name of responsible person

Dr. Shekoufeh Behdad

Street address

Shahid Sadoughi hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Sadoughi
University of Medical Sciences and Health Services

Full name of responsible person

Hassan Mozaffari

Street address

Shahid Sadoughi University of Medical Sciences and
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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

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences and Health Services

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**

Shahid Sadoughi hospital

Full name of responsible person

Shekoufeh Behdad

Position

anesthesiology assistant professor

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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*