Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The evaluation of the effect of infusion of ketofol on hypotension due to spinal anesthesia in cesarean section

Protocol summary

Summary

The purpose of this study is to compare the effect of infusion of ketofol on sedation score and hemodynamic variables of women who undergoing cesarean section under spinal anesthesia.In this double blind randomized clinical trial study, 60 ASA class I,18-40 years old patients randomly receive ketofol 1/10(infusion of 15 ml in 1 hour) or placebo(normal saline) during surgery.Sedation level of the patients is evaluated by sedation score every 15 minutes during the surgery.Systolic, diastolic, mean arterial pressures and heart rate measure every 3 minutes after spinal anesthesia until the end of surgery.Finally sedation score and hemodynamic variables(systolic, diastolic and mean arterial pressure, heart rate) are compared betwween two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509282963N23**
Registration date: **2016-02-23, 1394/12/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-23, 1394/12/04

Registrant information

Name

Shekoufeh Behdad

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 1386

Email address

drbehdad@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2015-10-13, 1394/07/21

Expected recruitment end date

2015-12-12, 1394/09/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of the effect of infusion of ketofol on hypotension due to spinal anesthesia in cesarean section

Public title

The evaluation of the effect of administration of ketofol on hypotension due to regional anesthesia in cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria:18-35 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; polyhydroamnious.

Age

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

Gender

Female

Phase
N/A
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
Shahid Sadoughi University of Medical Sciences
Street address
Bahonar Square
City
Yazd
Postal code
Approval date
2015-06-06, 1394/03/16
Ethics committee reference number
IR.SSU.MEDICINE.REC.1394.132

Health conditions studied

1

Description of health condition studied
ketofol
ICD-10 code
Y48.4
ICD-10 code description
Anaesthetic, unspecified

Primary outcomes

1

Description
Hemodynamic variables
Timepoint
every 3 min during the surgery
Method of measurement
monitoring

Secondary outcomes

1

Description
level of sedation
Timepoint
every 15 min during the surgery
Method of measurement
Ramsay score

Intervention groups

1

Description
infusion of ketofol 1/10(infusion of 15 ml in 1 hour)or during surgery in intervention group
Category
Treatment - Drugs

2

Description
infusion of normal saline(15 ml/h) during surgery in placebo group
Category
Treatment - Drugs

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, Ebnesina Blv, Safayieh, Yazd
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor of Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Dr Hassan Mozaffari
Street address
Bahonar Square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
vice chancellor of Shahid Sadoughi University of Medical Sciences
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 University of Medical Sciences
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Dr. Shekoufeh Behdad
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associate professor, Depatment of anestesiology
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Person responsible for updating data

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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