

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 between 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 accreta; gestational age < 28 weeks; polyhydramnios.

###### 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

**Full name of responsible person**

Dr. Shekoufeh Behdad

**Position**

associate professor, Department of anesthesiology

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**Fax****Email****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*