

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparison effect of intravascular administration of colloid versus crystalloid in prevention of hypotension after spinal anesthesia for cesarean section

#### Protocol summary

##### Summary

purpose: Comparison of fluid therapy and its effect on the prevention of maternal hypotension in pregnant women ASA I-II who are under spinal anesthesia for elective cesarean section. Design and criteria: This study is prospective, randomized, not-blinded and clinical trial. Setting and conduct: 100 patients scheduled for elective cesarean section under spinal anesthesia were randomly placed into four groups. 7 cc/kg colloid is given before and colloid with spinal anesthesia in group 1 and 2 , respectively, 10 cc/kg of crystalloid is given before and colloid with spinal anesthesia in group 3 and 4 , respectively. Vital signs are checked before and every 3 minutes to initial 10 minutes after spinal anesthesia and then every 5 minutes until recovery. Inclusion criteria: Candidates for elective cesarean surgery; ASA I-II; 18-40 years old. Exclusion criteria: Patients who received intravenous fluids before entering the operating room; BMI $\geq$ 30; ASA $>$ 3; Age less than 18 years and more than 40 years; Contraindications to spinal anesthesia procedures; Emergency cesarean section; Amount of intraoperative bleeding over 1000cc; History of hypertension and blood pressure in pregnancy; instances may increase the risk of bleeding and inertia. Main outcome: Primary outcomes; blood pressure and heart rate changes. Secondary outcomes; nausea & Vomiting, Chest discomfort, neonate apgar, Efedrin require. Intervention: Group1 ; Colloid recipient, 20 min before spinal anesthesia. Group 2 ; receiving Colloid while spinal anesthesia. Control group 1 ; Crystalloid recipient, 20 min before spinal anesthesia. Control group 2 ; Received spinal anesthesia with crystalloid.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013051612094N2**

Registration date: **2013-06-29, 1392/04/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-06-29, 1392/04/08

##### Registrant information

###### Name

Majid Razavi

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 915 110 8630

###### Email address

razavim@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Mashhad University of Medical Science

##### Expected recruitment start date

2012-11-21, 1391/09/01

##### Expected recruitment end date

2013-05-22, 1392/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison effect of intravascular administration of colloid versus crystalloid in prevention of hypotension after spinal anesthesia for cesarean section

**Public title**

Effect of fluid therapy in reducing complications of spinal anesthesia

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Candidates for elective cesarean surgery; ASA I-II; 18-40 years old. Exclusion criteria: Patients who received intravenous fluids before entering the operating room; BMI $\geq$ 30; ASA $>$ 3; Age less than 18 years and more than 40 years; Contraindications to spinal anesthesia procedures; Emergency cesarean section; Amount of intraoperative bleeding over 1000cc; History of hypertension and blood pressure in pregnancy; Instances may increase the risk of bleeding and inertia.

**Age**

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

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Ghoreishi apartment, Daneshgah st, Mashhad

**City**

Mashhad

**Postal code****Approval date**

2012-09-19, 1391/06/29

**Ethics committee reference number**

910046

**Health conditions studied****1****Description of health condition studied**

Spinal anesthesia

**ICD-10 code**

O29.5

**ICD-10 code description**

Other complications of spinal and epidural anaesthesia during pregnancy

**Primary outcomes****1****Description**

Blood pressure changes

**Timepoint**

Before spinal, every 3 minutes to initial 10 minutes, and then every 5 minutes until recovery.

**Method of measurement**

Perioperative monitoring

**2****Description**

Heart rate changes

**Timepoint**

Before spinal, every 3 minutes to initial 10 minutes, and then every 5 minutes until recovery.

**Method of measurement**

Perioperative monitoring

**Secondary outcomes****1****Description**

Nausea & Vomiting

**Timepoint**

Postoperative time

**Method of measurement**

Clinical observation

**2****Description**

Chest discomfort

**Timepoint**

Duration of Surgery

**Method of measurement**

Recorded in the questionnaire

**3****Description**

Neonate apgar

**Timepoint**

Duration of Surgery

**Method of measurement**

Recorded in the questionnaire

#### 4

**Description**

Efedrin require

**Timepoint**

Duration of Surgery

**Method of measurement**

Recorded in the questionnaire

### Intervention groups

#### 1

**Description**

Intervention group1 : Colloid infusion, 20 minutes before spinal anesthesia

**Category**

Prevention

#### 2

**Description**

Intervention group 2 : colloid infusion with spinal anesthesia

**Category**

Prevention

#### 3

**Description**

Control group1 : crystalloid infusion, 20 min before spinal anesthesia

**Category**

Prevention

#### 4

**Description**

control group 2 : crystalloid infusion with spinal anesthesia

**Category**

Prevention

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Majid Razavi

**Street address**

Department of Anesthesiology, Imam Reza Hospital, Ibne Sina st, Mashhad

**City**

Mashhad

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Vice Chancellor for Research, Mashhad University of Medical Science

**Full name of responsible person**

Mohsen Tafaghodi

**Street address**

Ghoreishi apartment, Daneshgah street, Mashhad

**City**

Mashhad

**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, Mashhad University of Medical Science

**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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Razavi

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

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**Web page address**

### Person responsible for scientific inquiries

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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*