

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

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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

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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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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

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Majid Razavi

Position

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Other areas of specialty/work

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