Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 befor 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≥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
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Iran (Islamic Republic of)
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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≥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
Befor 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
Befor 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
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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
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Assistant Professor
Other areas of specialty/work
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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