Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effects of crystalloid or colloid on maternal blood pressure after spinal anesthesia in cesarean section.

Protocol summary

Summary

Maternal hypotension is the commonest serious problem following spinal anesthesia for Cesarean section,with an incidence up to 83%.1 Volume preloading has been recommended for prevention of spinal-induced hypotension in this situation. However, controversy regarding the different preloading regimens remains unresolved.Recent studies have questioned the advantage of preloading with crystalloid in the prevention of spinal linduced hypotension in patients undergoing Cesarean section.We designed a randomized double-blind study to compare the incidence of hypotension in women undergoing elective cesarean delivery under spinal anesthesia who received 500 mL of colloid solution administered as a preload or coload versus a crystalloid solution adminstered as a preload. In this double-blind study, 105 patients were randomly assigned to receive a preload of 500 mL of hydroxyethyl starch (n = 35) or normal saline (n = 35) over a period of 15–20 min before initiation of spinal anesthesia or an identical fluid bolus of hydroxyethyl starch starting at the time of identification of cerebrospinal fluid (n =35) .perioperative maternal vital signs (Blood pressure, heart rate and arterial oxygen saturation) and also neonatal outcome including 1st and 5th apgar scores and arterial blood gas analyses are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201307215381N6**
Registration date: **2013-08-06, 1392/05/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-08-06, 1392/05/15

Registrant information

Name

Nadia Banihashem

Name of organization / entity

Babol University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

vice-chancellor Of Research Babol University Of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of crystalloid or colloid on maternal blood pressure after spinal anesthesia in cesarean section.

Public title

The effects of crystalloid or colloid on maternal blood pressure after spinal anesthesia in cesarean section.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:18 to 35 years pregnant women

candided for cesarean secton with ASA class I,II; parturients more than 37-week gestation. Exclusion criteria: Hypertension BP>140/90; DM;weight >100 kg; multiple gestation; Cardiovascular and cerbrovascular disease; Significant fetal abnormalities; contraindication of spinal anesthesia; mothers who are at the start of active phase of labor

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **105**

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
Ethics committee, Babol University of Medical Sciences

Street address
Daneshgah Sq, Ganjafrooz Ave

City
Babol

Postal code

Approval date
2013-07-22, 1392/04/31

Ethics committee reference number
2824/30/ژ/پ

Health conditions studied

1

Description of health condition studied
Cesarean Section

ICD-10 code
O74

ICD-10 code description
Complications of anaesthesia during labour and delivery

Primary outcomes

1

Description
Blood pressure

Timepoint
Baseline BP before Spinal anesthesia and every 3 minutes control until the end of surgery

Method of measurement
Non invasive BP Cuff

2

Description
PH of umbilical artery

Timepoint
Immediatly after birth

Method of measurement
ABG

Secondary outcomes

1

Description
Base excess

Timepoint
Base excess

Method of measurement
ABG

2

Description
Lactate of umbilical artery

Timepoint
Immediatly after birth

Method of measurement
ABG

3

Description
Infant Apgar

Timepoint
1 and 5 minutes after birth

Method of measurement
Apgar Score

4

Description
Heart rate

Timepoint
Before spinal anesthesia until the end of surgery every3 minutes

Method of measurement
pulse counting

Intervention groups

1

Description
Intervention 1: patients receive 500 mL of 6% hetastarch intravenously slowly before spinal anesthesia
Category
Prevention

2

Description
Intervention 2: patients receive 500 mL of 6% hetastarch intravenously as quickly as possible immediately after spinal anesthesia.
Category
Prevention

3

Description
Control group: patients receive 500 mL of ringer intravenously slowly before spinal anesthesia.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Ruhani Hospital
Full name of responsible person
Dr Nadia Banihashem
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor of Research Babol University Of Medical Sciences
Full name of responsible person
Dr Amrolah Mostafazadeh
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Daneshgah Square, Ganjafrooz Avenue, Vice-chancellor Of Research
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor of Research Babol 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
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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