

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 induced 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 administered 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

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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 section 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 cerebrovascular
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/پ/ج

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

City

Babol

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

Street address

Daneshgah Square, Ganjafrooz Avenue, Vice-chancellor Of Research

City

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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

Babol University of Medical Sciences

Full name of responsible person

Dr Nadia Banihashem

Position

Assistant Professor of Anesthesiology

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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