

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 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%.<sup>1</sup> 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

Babol University Of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 22 38296

###### Email address

nbanihashem@mubabol.ac.ir

##### 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 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/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

Babol

#### 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

##### Other areas of specialty/work

##### Street address

Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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## Person responsible for scientific inquiries

#### Contact

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##### Full name of responsible person

Dr Freshteh Naziri

##### Position

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## Person responsible for updating data

### Contact

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

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Daneshgah Square, Ganjafrooz Avenue

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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*