

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Pre-loading of Colloid-Crystalloid Combination on Maternal Hemodynamic Status Following Spinal Anesthesia for Cesarean Delivery

#### Protocol summary

##### Study aim

Effect of Pre-loading of Colloid-Crystalloid Combination on Maternal Hemodynamic Status Following Spinal Anesthesia for Cesarean Delivery

##### Design

Clinical trial with community-based and pragmatic control group, with parallel groups, blind, randomized,

##### Settings and conduct

70 pregnant women aged 18-40 years, with single term pregnancy candidate for cesarean section with spinal anesthesia are studying. The patients are randomly assigned to receive intravenous fluid in 2 study groups: the study group colloid + crystalloid solution (ringer) with equal volume and the placebo group received only crystalloids. After spinal anesthesia, the ringer solution was infused at 20 ml / kg / h until the end of the operation, and in each episode of hypotension, ml100 An extra ringer solution is prescribed. Hemodynamic bases are recorded every 2 minutes until delivery and then every 5 minutes until the end of the operation.. The total dosage of vasopressors is recorded. Side effects caused by hypotension including nausea and vomiting, restlessness, decreased consciousness and respiratory depression are recorded and treated. The Apgar score is recorded in minutes 1 and 5 of the birth.

##### Participants/Inclusion and exclusion criteria

inclusion criteria : - The desire to participate in the study  
- Elective cesarean candidate - A candidate for spinal anesthesia - ages 18-40 - Class I ASA grading - Single term pregnancy  
Non-inclusion criteria: - multifetal pregnancy - Weight over 100 kg and height less than 150 cm - History of systemic diseases - History of mental disorders - Contraindications for spinal anesthesia - fetal problems - Hypertension during pregnancy

##### Intervention groups

Intervention: colloid and crystalloid (ringer), 8ml/kg with equal volume  
Placebo: crystalloid (Ringer) 8ml/kg

##### Main outcome variables

Systolic blood pressure, Diastolic blood pressure, Mean

Arterial Pressure

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110712007013N22**

Registration date: **2019-06-16, 1398/03/26**

Registration timing: **retrospective**

Last update: **2019-06-16, 1398/03/26**

Update count: **0**

##### Registration date

2019-06-16, 1398/03/26

##### Registrant information

##### Name

Simin Atashkhoei

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3333 3806

##### Email address

atashkhoei@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-23, 1397/08/01

##### Expected recruitment end date

2019-04-21, 1398/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effect of Pre-loading of Colloid-Crystalloid Combination on Maternal Hemodynamic Status Following Spinal Anesthesia for Cesarean Delivery

**Public title**

Effect of Pre-loading of Colloid-Crystalloid Combination on Maternal Hemodynamic Status Following Spinal Anesthesia for Cesarean Delivery

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

The desire to participate in the study Elective cesarean candidate A candidate for spinal anesthesia ages 18-40 Class I ASA grading Single term pregnancy

**Exclusion criteria:**

- multiple pregnancy - Weight over 100 kg and height less than 150 cm History of systemic diseases (cardiovascular, liver, kidney, etc.)- History of mental disorder Contraindications for spinal anesthesia A history of allergy to Boyoukain Emergency cesarean section fetal problems(IUGR, meconium excretion, asyphexy ...) Hypertension during pregnancy Starch allergy

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After approving the Ethics Committee of the Vice-Chancellor for Research and Technology of Tabriz University of Medical Sciences and obtaining informed written consent from patients, 70 healthy women with term and singleton pregnancy who are candidates for elective cesarean section with spinal anesthesia were selected by simple sequential sampling ( consecutive ) Were randomly assigned to two groups according to the order of their choice and using randomized software (Rand list online).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Anesthesiologist has the responsibility of anesthesiology, patient monitoring and preparation of study solutions, and the thesis student who is unaware of the study group. is responsible for collecting information and variables of patient.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

**Street address**

Al Zahra hospital, Artesh Jonoubi Ave

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

513765716

**Approval date**

2019-05-06, 1398/02/16

**Ethics committee reference number**

IR.TBZMED.REC.1398.120

**Health conditions studied****1****Description of health condition studied**

Effect of Pre-loading of Colloid-Crystalloid Combination on Maternal Hemodynamic Status Following Spinal Anesthesia for Cesarean Delivery

**ICD-10 code**

O74.6

**ICD-10 code description**

Other complications of spinal and epidural anaesthesia during labour and delivery

**Primary outcomes****1****Description**

severity of hypotension

**Timepoint**

Basic times, every two minutes to 10 minutes, then minutes 15, 20, 30. 45 and 60 and the end

**Method of measurement**

Automatic pressure gauge

**Secondary outcomes****1****Description**

severity of Changes in Mother's Heart Rate

#### **Timepoint**

Basic times, every two minutes to 10 minutes, then minutes 15, 20, 30, 45 and 60 and the end

#### **Method of measurement**

pulseoximetry

### **Intervention groups**

#### **1**

##### **Description**

Intervention group: The study group (35 cases (8ml / kg colloid + crystalloid solution (ringer) with equal volume

##### **Category**

Prevention

#### **2**

##### **Description**

Control group: The placebo group (35 cases) received only crystalloids at 8ml / kg in 15 minutes.

##### **Category**

Placebo

### **Recruitment centers**

#### **1**

##### **Recruitment center**

###### **Name of recruitment center**

Al Zahra Hospital, Operation Room and postoperative setting

###### **Full name of responsible person**

Dr. Simin Atashkhoei

###### **Street address**

Al Zahra hospital, Artesh Jonoubi Ave, Operating room, Dr. Simin Atashkhoyi

###### **City**

Tabriz

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###### **Phone**

+98 41 3553 9161

###### **Email**

satashkhoyi@gmail.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Tabriz University of Medical Sciences

###### **Full name of responsible person**

Dr. Abolghasem Jouyban

###### **Street address**

Tabriz University, Daneshgah Ave, Tabriz

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###### **Phone**

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###### **Email**

ajouyban@hotmail.com

###### **Web page address**

<https://researchvice.tbzmed.ac.ir/PChart/94/1/>

###### **Grant name**

###### **Grant code / Reference number**

###### **Is the source of funding the same sponsor organization/entity?**

Yes

###### **Title of funding source**

Tabriz University of Medical Sciences

###### **Proportion provided by this source**

100

###### **Public or private sector**

Public

###### **Domestic or foreign origin**

Domestic

###### **Category of foreign source of funding**

*empty*

###### **Country of origin**

###### **Type of organization providing the funding**

Academic

### **Person responsible for general inquiries**

##### **Contact**

###### **Name of organization / entity**

Tabriz University of Medical Sciences

###### **Full name of responsible person**

Dr. Simin Atashkhoyi

###### **Position**

Professor, Specialist in Anesthesiology

###### **Latest degree**

Specialist

###### **Other areas of specialty/work**

Anesthesiology

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### **Person responsible for scientific inquiries**

##### **Contact**

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## Person responsible for updating data

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**Other areas of specialty/work**

Anesthesiology

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available