

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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, 100 ml 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)

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+98 41 3333 3806

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

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Tabriz University, Daneshgah Ave, Tabriz

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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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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