Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Study aim
Effect of Pre-loading of Colloid-Crystaloid 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 aged18-40 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 group: 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 Siences

Country
Iran (Islamic Republic of)

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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-Crystaloid Combination on Maternal Hemodynamic Status Following Spinal Anesthesia for Cesarean Delivery

Public title
Effect of Pre-loading of Colloid-Crystaloid 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-Crystaloid 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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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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Specialist

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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