

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

A comparison of the effect of Ringer Lactate versus Sodium Chloride 0.9% on maternal and neonatal acid- base state in elective cesarean delivery

Protocol summary

Study aim

Comparison of the effect of Ringer Lactate versus Sodium Chloride 0.9% on maternal and neonatal acid-base state in elective cesarean delivery

Design

A prospective randomized controlled trial (RCT), community-based, with two parallel groups, double blinded, randomized, consisted of 48 pregnant women in two groups of 24

Settings and conduct

In this study, which will be performed in the obstetric operating room of Alzahra Hospital in Tabriz in 98, the effect of two types of serums Ringer lactate and sodium chloride 0.9% on the maternal and neonatal acid-base status on 48 patients will be compared. They randomly divided into two groups. All data from the study will be collected through a checklist. Anesthesiologist who collects the data and pregnant women undergoing cesarean section are also unaware of the division of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 48 term pregnant women with the physical status of the ASA Class I or II, aged 18 to 45 years old, candidate for elective cesarean with spinal anesthesia with informed consent. Exclusion criteria: Any contraindication of regional anesthesia, maternal concurrent disease, emergency cesarean

Intervention groups

In the Ringer lactate group (n = 24), during the cesarean section, the Ringer lactate serum and in the sodium chloride 0.9% (n = 24) sodium sodium chloride 0.9% will be infused to the mother.

Main outcome variables

maternal and neonatal acid-base status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180411039267N2**

Registration date: **2019-06-19, 1398/03/29**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-19, 1398/03/29**

Update count: **0**

Registration date

2019-06-19, 1398/03/29

Registrant information

Name

Reyhaneh Abri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3476 7121

Email address

re.abri@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-01, 1398/03/11

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effect of Ringer Lactate versus Sodium Chloride 0.9% on maternal and neonatal acid-base state in elective cesarean delivery

Public title

A comparison of the effect of Ringer Lactate versus Sodium Chloride 0.9% on maternal and neonatal acid-base state in cesarean

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term parturient (pregnancy age more than 37 weeks) with physical status II ASA class candidates for elective cesarean section with spinal anesthesia Age range 18 to 45 years old In Tabriz Alzahra hospital Informed consent

Exclusion criteria:

Any contraindication of regional anesthesia Gestational hypertension, preeclampsia, eclampsia, HELLP syndrome Hypersensitivity to local anesthetics Morbid obesity Maternal co-existing disease such as a history of heart disease, pulmonary, liver and kidney disease Emergency cesarean section like fetal bradycardia, placenta previa or other conditions of peripartum hemorrhage

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random numbers table, they will be randomly divided into two groups of 24 people in the study and 24 people in the control group. In such a way that in the event of odd, they would be in Ringer Lactate and in the event of even, they would be in Sodium Chloride 0.9% group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The administration of anesthesia and fluids (volume and type of serum) during anesthesia is performed by an anesthesiologist and anesthesia technician, and all data will be collected and recorded in the checklist by an anesthesiologist who is unaware of the division of the groups. Pregnant women undergoing cesarean section are also unaware of the division of the groups.

Placebo

Not 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

Department of Anesthesiology, Alzahra hospital, South artesh street

City

Tabriz

Province

East Azarbaijan

Postal code

5174815811

Approval date

2018-04-16, 1397/01/27

Ethics committee reference number

IR.TBZMED.REC.1397.034

Health conditions studied

1

Description of health condition studied

Intraoperative fluid therapy, maternal and neonatal acid-base state, elective cesarean delivery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

maternal acid- base state during elective cesarean

Timepoint

In operating room before the spinal anesthesia and after surgery (in recovery), an arterial blood sample will be analyzed for arterial blood gases (ABG).

Method of measurement

In the ABG sample, the factors PH, HCO₃, Base Excess, PCO₂, Po₂, Hb, Hct will be analyzed and will be recorded in the checklist for this purpose.

Secondary outcomes

1

Description

neonatal acid- base state during elective cesarean

Timepoint

Immediately after delivery and the umbilical cord closure, an umbilical artery blood sample will be sent for analysis of arterial blood gas (ABG).

Method of measurement

In the ABG sample, the factors PH, HCO₃, Base Excess, PCO₂, Po₂, Hb, Hct will be analyzed and will be recorded in the checklist for this purpose.

Intervention groups

1

Description

Intervention group: In 24 pregnant women, infusion of lactate ringer serum with dose of volume therapy rule(Deficit+ Maintenance+ Loss+ Third space+ Compensated volume expansion) will begin before surgery and will continue until delivery of mother to the ward.

Category

Treatment - Other

2

Description

Control group: In 24 pregnant women, infusion of Sodium Chloride 0.9% serum with dose of volume therapy rule(Deficit+ Maintenance+ Loss+ Third space+ Compensated volume expansion) will begin before surgery and will continue until delivery of mother to the ward.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Reyhaneh Abri

Street address

Alzahra hospital, South artesh street

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3553 9163

Email

alzahrahosp@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Jouyban

Street address

International Relations Office, No 2 Central Building,
Tabriz University of Medical Sciences, University
Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 7310

Email

research-vice@tbzmed.ac.ir

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

Reyhaneh Abri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Department of Anesthesiology, Alzahra Hospital,
South Artesh Street

City

Tabriz

Province

East Azarbaijan

Postal code

5174815811

Phone

+98 41 3553 9163

Email

reyhane.abri@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Reyhaneh Abri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Operating room-alzahra hospital- south artesh st

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3476 7121

Email

reyhane.abri@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Reyhaneh Abri

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Operating room-alzahra hospital- south artesh st

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East Azarbaijan

Postal code

5138663134

Phone

+98 41 3476 7121

Email

reyhane.abri@gmail.com

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