

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Comparison of the effect of serum administration of 1.3 and 2.3% Ringer Lactate and Normal Saline on duration of labor, Cesarean section, Serum bilirubin and glucose level and PH of neonatal cord blood in neonatal women undergoing labor induction

#### Protocol summary

##### Study aim

Determination of the effect of normal saline-1.3 and 2.3-serum administration on the duration of labor in infants born to women undergoing labor induction

##### Design

This study is a two-way blind clinical trial. Individuals are randomized by table of numbers and divided into three groups, then a number is given to each person. The sample size was 450 people. This study is two-way blind, so that the subject and statistical analyst of the situation. The allocation of groups was unaware that only the supervisor was aware of the allocation of groups. The trial phase could not be defined for this study

##### Settings and conduct

Patients referred to Akbarabadi Hospital who are candidates for entry to study. An equal number of pregnant women entered: In group 1 serum normal saline is injected during the labor - group 2 serum normal saline is injected during the labor & group 3 serum ringer is injected during the labor. Injection rate is 125 cc per min for all groups, from the time entry to the delivery room until the end of the birth. The study is two-way blind, and the blinded patient and epidemiologist. And a Supervisor is informed

##### Participants/Inclusion and exclusion criteria

A woman with Gravid 1 pregnancy with a Bishop score of less than 4. Single pregnancy. Cephalic Presentation. Gestational age greater than 37 weeks. NO entry: A woman with Gravid 1 pregnancy with a Bishop score of bigger than 4. Multiple pregnancy. breach Presentation. Gestational age less than 37 weeks

##### Intervention groups

This study has 3 intervention groups. Group 1 is injected with normal saline during labor. Group 2 is injected with 1.3-2.3 during labor. Group 3 is injected with ringer during labor. The injection rate for all groups is 125 cc per

minute from the time of entry into the delivery room until the end of the birth. Control group: Not applicable

##### Main outcome variables

Cesarean rate Serum bilirubin level Baby umbilical cord blood pH The duration of labor

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200202046346N1**

Registration date: **2020-04-20, 1399/02/01**

Registration timing: **retrospective**

Last update: **2020-04-20, 1399/02/01**

Update count: **0**

##### Registration date

2020-04-20, 1399/02/01

##### Registrant information

##### Name

Mina Momeni

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3625 6451

##### Email address

momeni.mi@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-25, 1398/09/04

**Expected recruitment end date**

2020-02-29, 1398/12/10

**Actual recruitment start date**

2019-11-25, 1398/09/04

**Actual recruitment end date**

2020-02-29, 1398/12/10

**Trial completion date**

2020-02-29, 1398/12/10

**Scientific title**

Comparison of the effect of serum administration of 1.3 and 2.3% Ringer Lactate and Normal Saline on duration of labor, Cesarean section, Serum bilirubin and glucose level and PH of neonatal cord blood in neonatal women undergoing labor induction

**Public title**

The effect of different types of serum therapy on maternal and fetal outcomes during childbirth

**Purpose**

Other

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

Gravid one Bishop Score<4 Pregnancy single fetus Cephalic presentations Gestational age more than 37 weeks

**Exclusion criteria:**

Multiparity Known heart disease that can't handle this fluid volume Induction contraindications Such as Intrauterine growth restriction (IUGR); Suspicion of Cephalopelvic disproportion (CPD); Breech show member Patients undergoing cervical ripening

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **450**

Actual sample size reached: **450**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After consciously satisfying the individuals, they are randomized by the number table method and divided into three groups. In this method, a number of cards or letters are selected by the researcher as the first group and the same. The number of cards is considered for the next group; then by merging the tasks together (On playing cards) A card is taken out and its allocation is recorded, and that card is returned to the other cards after leaving. Then the cards are merged again and another card is taken out. This process continues until a random sequence is reached according to the sample size. Also, the number of cards or names is not necessarily equal to the total number of samples. For

example, in a three-group study with a sample size of 300 people and a group ratio of 1: 1: 3 cards can be used. He prepared for each group. The software and people are divided into three groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Thus, the subject and statistical analyst are unaware of the status of the allocation of the three groups to the study. The subject is not aware of the allocation status to the groups. The researcher who measures clinical and diagnostic measurements will not be aware of the individual's condition, and the statistical advisor will be unaware of the individual's allocation to the study groups. Only the supervisor, appointed by the university, was aware of the allocation of groups.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Iran University of Medical Sciences

**Street address**

Vice Chancellor for International affairs, Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, 1449614535, IRAN

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2019-11-24, 1398/09/03

**Ethics committee reference number**

IR.IUMS.FMD.REC.1398.368

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

labor

**ICD-10 code****ICD-10 code description****Primary outcomes**

## 1

### **Description**

The duration of labor

### **Timepoint**

At the beginning of labor and after delivery

### **Method of measurement**

the watch

## 2

### **Description**

Cesarean section

### **Timepoint**

Postpartum

### **Method of measurement**

Percent

## 3

### **Description**

Serum bilirubin level

### **Timepoint**

After labor

### **Method of measurement**

Dedicated experiments

## 4

### **Description**

Baby umbilical cord blood pH

### **Timepoint**

After birth

### **Method of measurement**

Dedicated experiments

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

intervention Group 1: In this study, an equal number of pregnant women G 1 with Bishop Score less than 4 who have a pregnancy termination indication are included in the study. The first group during delivery (when the patient is brought to the delivery room to induce labor and is ready to give birth on a special bed) is injected with 125 cc of normal saline per minute and continues until after delivery and the birth of the baby, then will be disconnected.

### **Category**

Other

## 2

### **Description**

intervention Group 2: In this study, an equal number of pregnant women G 1 with Bishop Score less than 4 who have a pregnancy termination indication are included in

the study. The first group during delivery (when the patient is brought to the delivery room to induce labor and is ready to give birth on a special bed) is injected with 125 cc of 1/3-2/3 serum per minute and continues until after delivery and the birth of the baby, then will be disconnected.

### **Category**

Other

## 3

### **Description**

intervention Group 2: In this study, an equal number of pregnant women G 1 with Bishop Score less than 4 who have a pregnancy termination indication are included in the study. The first group during delivery (when the patient is brought to the delivery room to induce labor and is ready to give birth on a special bed) is injected with 125 cc of ringer serum per minute and continues until after delivery and the birth of the baby, then will be disconnected.

### **Category**

Other

## **Recruitment centers**

## 1

### **Recruitment center**

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

Shahid Akbarabadi hospital

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

Mina Momeni

#### **Street address**

Shahid Akbarabadi hospital; Molavi street; Tehran; Iran 1168743514

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1168743514

#### **Phone**

+98 21 5560 6034

#### **Email**

akbarabadihosp@yahoo.com

#### **Web page address**

<https://cрта.iu.ms.ac.ir/>

## **Sponsors / Funding sources**

## 1

### **Sponsor**

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

Iran University of Medical Sciences

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

Vice Chancellor for Research, Iran University of Medical Sciences

#### **Street address**

Vice Chancellor for International affairs, Iran University of Medical Sciences, Shahid Hemmat

Highway, Tehran, 1449614535, IRAN

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**Email**

ivco@iums.ac.ir

**Web page address**

https://iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Mina Momeni

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mina Momeni

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available