Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 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 bornto 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 sizewas 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 group1 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 is125cc per min for all groups, from the time entery 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 Gravid1pregnancy with a Bishop score of less than 4 Single pregnancyCephalic Presentation Gestational age greater than37 weeksNO entry: A woman with Gravid1pregnancy with a Bishop score of bigger than 4 multiple pregnancy breach PresentationGestational age less than37weeks

Intervention groups

This study has 3 intervention groups.Group1is injected with normal saline during labor.Group1is injected with1.3-2.3 during labor.Group3 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

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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, theIn 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
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Tehran
Province
Tehran
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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 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 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
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Shahid Akbarabadi hospital; Molavi street; Tehran; Iran 1168743514
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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
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Vice Chancellor for International affairs, Iran University of Medical Sciences, Shahid Hemmat

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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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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