Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of intravenous syntocinone injection on the third stage of labor in pregnant women

Protocol summary

Study aim
The effect of intravenous syntocinone injection on the third stage of labor in pregnant women

Design
Clinical trial with controlled group, parallel design, double-blinded, randomized; phase 3 on 100 pregnant women. Randomization will be conducted using block randomization method via Rand function in Excel software

Settings and conduct
The present study will be conducted at hazrat zeinab hospital affiliated to Shiraz University of Medical Sciences,Shiraz -Iran. The study designed as double blinded in which the participants and outcome assessors will be masked to their assignment

Participants/Inclusion and exclusion criteria
Women with a delivery rate of 0-2 who have a spontaneous vaginal delivery and do not have any complications during pregnancy and childbirth will be included in the study. Women who have a disorder during pregnancy or childbirth will be excluded from the study

Intervention groups
The studied pregnant women will be divided into two groups of intervention and control.. In the experimental group, 10 international units of oxytocin are injected into the umbilical vein (near the entrance to the vagina intraitus) immediately after the baby is born and the umbilical cord is severed. In the control group, 1 cc of normal saline is injected in the same place

Main outcome variables
Blood pressure before and 30 and 60 minutes after delivery, hemoglobin and hematocrit levels before and 6 hours after delivery, duration of the third stage of labor, mean pain intensity score of the third stage of labor, placental characteristics, postpartum complications, manual placental removal

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20110103005534N2**
Registration date: **2022-07-23, 1401/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-23, 1401/05/01**
Update count: **0**

Registration date
2022-07-23, 1401/05/01

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
07116474254
Email address
azimas@sums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-07-16, 1401/04/25
Expected recruitment end date
2022-09-22, 1401/06/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of intravenous syntocinone injection on the

third stage of labor in pregnant women

Public title
The effect of intravenous syntocinone injection on the third stage of labor

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Term pregnancy (37-42 weeks) Single pregnancy vertex presentation Age 18- 35 years Number of deliveries 0-2 Spontaneous onset of labor pains No chronic diseases (heart disease, hypertension and diabetes) Absence of high-risk pregnancies (gestational hypertension, decreased fetal motility, fetal death, amniotic polyhydramnios and oligohydramnios known by ultrasound, rupture of membranes more than 12 hours, history of infertility) alive fetus Birth weight between 4500-2500 grams Prenatal hemoglobin more than 10 grams per deciliter absence of placenta previa absence of placenta abruption No history of any bleeding during pregnancy No curettage history Absence of any scar on the uterus Do not take anticoagulants

Exclusion criteria:
Reluctance to continue participating in the study Disorders in the progress of labor prolong labor (more than 20 hours) precipitate labor(less than 3 hours) Blood pressure of 140/90 mm Hg or more during the study Disorders in labor (prolong labor, dystocia, placenta abruption , umbilical cord prolapse, etc.) Manual Removal of the Placenta Abnormal fetal heart rate patterns leading to cesarean section Lack of progress of labor that leads to cesarean section Expansion of the episiotomy Excessive postpartum hemorrhage (more than 500 cc) Using vacuum postpartum re-manipulation of the perineum

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be assigned to the experimental and control groups by permutation random block method.After selection samples, using random numbers table and permutation method We assign groups B and A. Permutations of A and B are AB and BA that the numbers 0 to 4 are assigned to the AB permutation and the numbers 5 to 9 are assigned to the BA permutation

Blinding (investigator's opinion)
Double blinded

Blinding description
Both the researcher and parturient will be blinded to the study. In both groups, according to the hospital routine, immediately after the birth of the baby, 20 international units of oxytocin solution is injected as an intravenous infusion. In the intervention group, the amount of 10 international units Oxytocin in the umbilical vein (near the intraitus vaginal entrance) immediately after birth the baby and the umbilical cord cut, are injected. In the control group, 1 cc of normal saline is injected in the same place. Both the researcher and parturient were blinded to the study, and the solution of syntocinon and normal saline was prepared in similar syringes by the midwife in the delivery room and given to the researchers. Also, the outcome assessor and statistical analysts will be blinded by the allocation of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
No 60 ,Zand Street, Shiraz University of Medical Sciences,Shiraz,Iran

City
Shiraz

Province
Fars

Postal code
7134814336

Approval date
2015-05-17, 1394/02/27

Ethics committee reference number
IR.SUMS.REC.1394.33

Health conditions studied

1

Description of health condition studied
Delivery outcome

ICD-10 code
Z37

ICD-10 code description
Outcome of delivery

Primary outcomes

1

Description
Hemoglobin and hematocrit levels
Timepoint
Before intervention and 6 hours after delivery
Method of measurement
Using a microcentrifuge

2

Description
Duration of the third stage of labor
Timepoint
Third stage of labor
Method of measurement
On a minute basis

3

Description
Pain intensity in the third stage of labor
Timepoint
Third stage of labor
Method of measurement
Visual pain ruler

4

Description
Systolic and diastolic blood pressure 30 and 60 minutes after delivery
Timepoint
30 and 60 minutes after delivery
Method of measurement
Standard mercury blood pressure monitor

5

Description
Placenta characteristics (weight - diameter - exit method - anomalies)
Timepoint
After delivery of placenta
Method of measurement
observation-meter-scale

6

Description
Manual Removal of the Placenta
Timepoint
After placenta delivery
Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 10 units of Oxytocin is injected into the umbilical vein (near the entrance to the vagina intraitus) immediately after the baby is born and the umbilical cord is cut in postpartum women
Category
Treatment - Drugs

2

Description
Control group: One ml of normal saline is injected into the umbilical vein (near the entrance to the vagina intraitus) immediately after the baby is born and the umbilical cord is cut in postpartum women
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Zeinab hospital
Full name of responsible person
Sara Azima
Street address
Holy Defense Square
City
Shiraz
Province
Fars
Postal code
7153513311
Phone
+98 71 3726 6811
Email
azimas@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpoor
Street address
No 60 ,Zand Street, Shiraz University of Medical Sciences,Shiraz,Iran
City
Shiraz
Province
Fars
Postal code
7134814336

Phone
+98 71 3230 5410
Email
info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Sara Azima
Position
instructor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No 73,School of Nursing and Midwifery,Nemazee squair, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71 3647 4258
Email
azimas@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sara azima
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No 73,School of Nursing and Midwifery,Nemazee squair, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71 3647 4258
Email
azimas@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sara Azima
Position
Instructor
Latest degree
Master
Other areas of specialty/work
Midwifery
Street address
No 73,School of Nursing and Midwifery,Nemazee squair, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7193613119
Phone
+98 71 3647 4258
Email
azimas@sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document

Primary outcome data after making participants unrecognizable will be released

When the data will become available and for how long

6 months after publishing the results of primary outcome

To whom data/document is available

Any researchers will have access to the data after allowance of corresponding author

Under which criteria data/document could be used

Performing any analysis to any data resulted form this study will be allowed only with the permission of corresponding author

From where data/document is obtainable

Correspondance author

What processes are involved for a request to access data/document

After requesting for data, correspondence will check the authorization and then they will be informed about it

Comments