

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 in utero) 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 Memarpour

##### 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

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

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**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 from 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**