

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Jun 2026

### Comparison the effect of interrupted and continuous Oxytocin during active phase on duration of labor, maternal and neonatal outcomes in normal vaginal delivery labor

#### Protocol summary

##### Summary

**Objectives:** The aim of this study is to investigate the effect of early interrupting of Oxytocin compared to continuing of Oxytocin during the active phase of labor, cesarean risk during labor, maternal and neonatal outcomes; so we can increase the mother and infant safety and reach to hospital aims for Mother-Baby Friendly Hospital which is normal vaginal delivery with minimal intervention. **Design, Setting and conduct:** In a prospective randomized clinical trial, all patients who will randomize by blocks divide into two groups. The first group will receive Oxytocin which continue until delivery and in second group Oxytocin discontinued in initial of active phase. **Participants, inclusion and exclusion criteria:** All pregnant women with gestational age  $\geq 34$  weeks and vertex presentation and an indication for induction (gestational age less than 42 weeks, rupture of membranes - oligohydramnios, high blood pressure) enrolled in study. **Inclusion criteria** included singleton pregnancy, vertex presentation, estimated weight  $< 4$  kg, gestational age  $> 34$  weeks without any contraindication for NVD. **Exclusion criteria** included any contraindication for normal vaginal delivery or administration of Oxytocin such as malpresentation, Placenta Previa, previous cesarean section cervix surgery, Twin or multiple pregnancy, uncertain fetal heart rate. **Intervention:** All women will receive 10 units of Oxytocin by infusion. Oxytocin initiated equal to 2mu/min and increased 2mu/min every 15 minutes up to mg 32mu/min or until contractions of uterine reach to 3-5 per 10 minutes. Oxytocin is maintained at a constant level at this time. After the beginning of the active phase (cervical dilatation 4 cm) then patients divided into 2 groups, in the first group Oxytocin continues until delivery and in the other group will discontinue at the beginning of the active phase. **Main outcome:** Patients undergoing vaginal exam to evaluate the progress of labor and fetal heart

rate and uterine contractions is controlled every 15 minutes . If in second group within 2 hours cervix dilatation do not progress or numbers of contractions reach to less than 3 contractions per 10 minutes, Oxytocin start again. Also, if there is Non-Reassuring Fetal Heart Rate Patterns in first group, Oxytocin will discontinue. Duration of the active phase, total duration of labor, amount of administrated Oxytocin intake, maternal complications (including uterus hyperstimulation which is 6 or more uterine contractions per 10 minutes), Non-Reassuring Fetal Heart Rate Patterns, abnormal postpartum hemorrhage and type of delivery (caesarean or normal) and its reason, neonatal outcomes including fifth minute Apgar score, and admission to NICU evaluate in both groups. The decision for cesarean delivery will make based on obstetrical indications includes decelerations and lack of progress and is same in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013102211019N2**  
Registration date: **2013-12-20, 1392/09/29**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-12-20, 1392/09/29

##### Registrant information

###### Name

Mojgan Rahmanian

###### Name of organization / entity

Semnan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

**Phone**

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**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice Chancellor for Research, Semnan University of Medical Sciences

**Expected recruitment start date**

2013-11-22, 1392/09/01

**Expected recruitment end date**

2014-05-21, 1393/02/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the effect of interrupted and continuous Oxytocin during active phase on duration of labor, maternal and neonatal outcomes in normal vaginal delivery labor

**Public title**

Effect of interrupted and continuous Oxytocin on duration of labor

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Singleton pregnancy; Vertex presentation; Estimated weight <4 kg; gestational age> 34 weeks; Absence of any contraindication for NVD. Exclusion criteria: Any contraindication for normal vaginal delivery; Any contraindication for administration of Oxytocin such as Malpresentation, Placenta Previa; Previous cesarean section; Cervix surgery; Twin or multiple pregnancy; Uncertain fetal heart rate.

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: 70

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics Committee Of Semnan University of Medical Sciences

**Street address**

Basidj Boulevard

**City**

Semnan

**Postal code****Approval date**

2013-10-07, 1392/07/15

**Ethics committee reference number**

92/352431

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

Normal Vaginal Delivery

**ICD-10 code**

O80.0

**ICD-10 code description**

Spontaneous vertex delivery

**Primary outcomes****1****Description**

Active delivery phase

**Timepoint**

Every 15 minutes after intervention

**Method of measurement**

Clinical examination

**Secondary outcomes****1****Description**

Cervix dilatation; Fetal Heart Rate Patterns

**Timepoint**

2 hours after intervention

**Method of measurement**

Clinical examination

**Intervention groups**

## 1

### Description

All patients in first group receive 10 units of oxytocin by infusion. Oxytocin initiated equal to 2mu/min and increased 2mu/min every 15 minutes up to mg 32mu/min or until contractions of uterine reach to 3-5 per 10 minutes. Oxytocin is maintained at a constant level at this time. After the beginning of the active phase (cervical dilatation 4 cm) oxytocin continues until delivery.

### Category

Treatment - Other

## 2

### Description

All women in second group will receive 10 units of oxytocin by infusion. Oxytocin initiated equal to 2mu/min and increased 2mu/min every 15 minutes up to mg 32mu/min or until contractions of uterine reach to 3-5 per 10 minutes. Oxytocin is maintained at a constant level at this time. After the beginning of the active phase (cervical dilatation 4 cm) then oxytocin will be stopped at the beginning of the active phase.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir Al Momenin Hospital

##### Full name of responsible person

Maryam Sina

##### Street address

Imam Hussein square

##### City

Semnan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Semnan University of Medical Sciences

##### Full name of responsible person

Raheb Ghorbani

##### Street address

Basidj Boulevard

##### City

Semnan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice chancellor for research, Semnan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Maryam Sina

#### Position

Obstetrics and Gynecology resident

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Position

Gynecologists

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Mehrdad Zahmatkesh

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Research expert

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*