# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Comparison of the effects of intramuscular methylergonovine, intravascular oxytocin, and sublingual prostaglandin (misoprostol) in active management of the third stage of labor

## Protocol summary

**Summary**
In this study, 150 pregnant women with singleton low risk pregnancies and live fetuses will enroll and randomly divided into three groups of 50 patients. The participants will observed until labor. After delivery of the anterior shoulder, the first group will given 400 µg of sublingual misoprostol; the second group, a 0.2 mg single dose of intramuscular methylergonovine, and the third group receive 20 units of intravascular oxytocin,(these drugs are given only one time). Three parameters will be measured and compared between these groups: the amount of hemorrhage during third and fourth stages of labor, the duration of the third stage of labor, and the degree of decrease in blood hemoglobin level 24 hours after delivery

## General information

**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT201106143756N2**
Registration date: **2011-09-20, 1390/06/29**
Registration timing: **retrospective**

Last update:
Update count: **0**
**Registration date**
2011-09-20, 1390/06/29

**Registrant information**
**Name**
Tarlan Hamidehkhoo
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Ahvaz University of Medical Sciences
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**Recruitment status**
**Recruitment complete**
**Funding source**
Ahvaz Jundishapour University Of Medical Scienses

**Expected recruitment start date**
2010-11-21, 1389/08/30
**Expected recruitment end date**
2011-04-19, 1390/01/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Comparison of the effects of intramuscular methylergonovine, intravascular oxytocin, and sublingual prostaglandin (misoprostol) in active management of the third stage of labor

**Public title**
Comparison of the effects of intramuscular methylergonovine, intravascular oxytocin, and sublingual prostaglandin in prevention of post partum hemorrhage
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
Inclusion criteria: women with singleton pregnancy; low risk pregnancies;live fetuses; cephalic presentation; normal blood pressure;no history of postpartum haemorrhage;no history of coagulation disorders;no history of heart disease;no history of seizure; no sever anemia(Hb less than 7) exclusion criteria: uterine atonia ;large lacerations with massive bleeding

**Age**
From **20 years** old to **40 years** old
**Gender**
Female

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **150**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Vice-Chancellor For Research, Ahvaz University of Medical Scienses
**Street address**
Vice-Chancellor For Research, Ahvaz University of Medical Scienses ,golestan blvd,daneshgah square
**City**
Ahvaz
**Postal code**
**Approval date**
2010-11-06, 1389/08/15
**Ethics committee reference number**
ETH034

## Health conditions studied

### 1

**Description of health condition studied**
Post partum haemorrhage
**ICD-10 code**
072.1
**ICD-10 code description**
Other immediate postpartum haemorrhage

## Primary outcomes

### 1

**Description**
Volume of Postpartum haemorrhage
**Timepoint**
One hour after delivery
**Method of measurement**
Scaled container and scaling of the pad in mililiter

### 2

**Description**
Amount of hemoglobin drop
**Timepoint**
24 houres after delivery
**Method of measurement**
Check of hemoglobin

### 3

**Description**
Duration of the third phase of parturation
**Timepoint**
From fetus delivery to expression of placenta
**Method of measurement**
Check of the time in second

## Secondary outcomes

### 1

**Description**
Nausia , vomitting, diarrhia and fever due to misoprostole
**Timepoint**
1 and 2 hour after delivery
**Method of measurement**
Patient's symptoms and vital siqns

### 2

**Description**
Hypotension and water intoxication
**Timepoint**
1 and 2 hour after delivery
**Method of measurement**
Patient's symptoms and vital siqns

### 3

**Description**
Transient hypertension due to metergin
**Timepoint**
1 and 2 hour after delivery
**Method of measurement**
Patient's symptoms and vital siqns

## Intervention groups

### 1

**Description**
After delivery of anterior shoulder 0.2mg metergin IM,single dose
**Category**

Prevention

**2**

**Description**
After delivery of the anterior shoulder 20 unit oxytocin iv infusion,single dose
**Category**
Prevention

**3**

**Description**
After delivery of anterior shoulder 400 microgram misoprostole sublingual,single dose
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Ahvaz Emam Khomeini hospital
**Full name of responsible person**
Leila Fathinejad
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Emam Khomeini hospital,ahvazian street,Azadegan avenue
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Jundishapour University Of Medical Scienses
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Dr. Mostafa Feghhi, Vice-Chancellor For Research
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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**
Jundishapour University Of Medical Scienses
**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

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Associated professor
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## Person responsible for updating data

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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*