

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of the effect of rectal Misoprostol and Syntometrin in prevention of post partum hemorrhage

#### Protocol summary

##### Summary

This is a randomized double blind clinical trial to investigate the effect of rectal Misoprostol and Syntometrin in prevention of post partum hemorrhage. 200 pregnant women referred to the Shabihkhany hospital in Kashan for vaginal delivery were randomly assigned into one of following groups: The first group received 1 ml Syntometrine IM and the second group received 600 mgr misoprostol rectal after placental expulsion. Then, all patients were assessed 0.5 and 1 hour after delivery for uterine tonicity, pulse rate and blood pressure. 24 hours after delivery hemoglobin was checked for estimation of postpartum hemorrhage. Need for uterotonic drugs and rate of adverse effects were also compared between the intervention groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201008212854N5**

Registration date: **2010-09-09, 1389/06/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-09-09, 1389/06/18

##### Registrant information

##### Name

Masoumeh Abedzadeh Kalahroudi

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36 1555 0021

##### Email address

abedzadeh@kaums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Basic Science of Kashan University of Medical Sciences

##### Expected recruitment start date

2010-04-21, 1389/02/01

##### Expected recruitment end date

2010-09-21, 1389/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of rectal Misoprostol and Syntometrin in prevention of post partum hemorrhage

##### Public title

Comparison of the effect of rectal Misoprostol and Syntometrin in prevention of post partum hemorrhage

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: pregnant women with single pregnancy and candidate for vaginal delivery Exclusion criteria: Presence of preeclampsia, hypotension, heart disease, asthma, hypertonic uterus, uterine rupture, or vaginal and cervical laceration, being high risk for postpartum bleeding such as: multiparity, uterine myoma, history of postpartum bleeding, or need for uterine curettag

##### Age

From **15 years** old to **50 years** old

##### Gender

Female

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: **200**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Kashan University of Medical Sciences

##### Street address

Ravand road Kashan University of Medical

##### City

Kashan

##### Postal code

#### Approval date

2010-08-02, 1389/05/11

#### Ethics committee reference number

1207/1/5/29/پ

## Health conditions studied

### 1

#### Description of health condition studied

Post partum hemorrhage

#### ICD-10 code

Z39

#### ICD-10 code description

Postpartum care and examination

## Primary outcomes

### 1

#### Description

Uterine tone

#### Timepoint

0.5 and 1 hours after delivery

#### Method of measurement

Assessment of uterine tone

### 2

#### Description

Hemoglobin level

#### Timepoint

Before and 24 hours after delivery

#### Method of measurement

Hemoglobine assessment

### 3

#### Description

Blood Pressure

#### Timepoint

immadiate, 30 minute and 1 hour after delivery

#### Method of measurement

by sphygnomanometer

### 4

#### Description

pulse

#### Timepoint

immadiately, 30 minute and 1 hours after delivery

#### Method of measurement

by counting

## Secondary outcomes

### 1

#### Description

Adverse effects

#### Timepoint

During Hospitalization

#### Method of measurement

Observation of adverse effects

### 2

#### Description

Need to administration of utertonic drug

#### Timepoint

During 24 hours after delivery

#### Method of measurement

dosage and amount of drug

## Intervention groups

### 1

#### Description

Syntometrin, 1 ml, IM in third stage of labour after placental expulsion

#### Category

Prevention

### 2

#### Description

Misoprostol, 1 ml, Rectal suppository in third stage of labour

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shabihkhany Hospital

**Full name of responsible person**

Dr. Mansoureh Samimi

**Street address**

Shabihkhany Hospital, Beheshti Street

**City**

kashan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for Basic Sciences, Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Atlasi Mohammad Ali

**Street address**

Ravand road Kashan University of Medical Sciences

**City**

kashan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice chancellor for Basic Sciences, Kashan 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**

Kashan University of Medical Sciences

**Full name of responsible person**

Masoumeh Abedzadeh kalahroudi

**Position**

MSc in Midwifery

**Other areas of specialty/work**

**Street address**

Midwifery Faculty, Kashan University of Medical

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Mansoureh Samimi

**Position**

Obstetrician and Gynecologist

**Other areas of specialty/work**

**Street address**

Shabihkhany Hospital, Beheshti Street

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## Person responsible for updating data

#### Contact

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**Other areas of specialty/work**

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**Phone**

**Fax**

**Email**

**Web page address**

## 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*