

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### Comparing the effect of sublingual Misoprostol versus intravenous Oxytocin in the management of the third stage of labor

#### Protocol summary

##### Summary

This study will be performed on 200 primiparous women in Al-zahra hospital of Rasht, Iran. The women will be divided into two groups randomly. One group (Intervention group) will be treated with 400 microgram of sublingual Misoprostol plus 20 ml of distilled water as placebo and another group (control group) will be treated with 20ml of Intravenous Oxytocine plus two sublingual placebo tablet. The drugs will be prescribed by a delivery agent to mothers immediately after neonatal birth. The amount of lost blood in third stage of delivery will be measured by scaled dish. Also we weigh Blood gauzes during the repair of episiotomy by a digital scale. Additionally Patients hemoglobin level will be evaluated before and 12 hours after delivery.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138902293964N1**

Registration date: **2010-08-23, 1389/06/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-08-23, 1389/06/01

##### Registrant information

##### Name

Fereshte Fakoor

##### Name of organization / entity

Guilan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1322 5624

##### Email address

fakoor@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research - Guilan university of medical sciences

##### Expected recruitment start date

2010-08-23, 1389/06/01

##### Expected recruitment end date

2011-08-23, 1390/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of sublingual Misoprostol versus intravenous Oxytocin in the management of the third stage of labor

##### Public title

Comparing the effect of sublingual Misoprostol versus intravenous Oxytocin in the management of the third stage of labor

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: primiparity, informed consent, entering the labour spontaneously - Exclusion criteria: multyparity, be longed induction (>12 hours), past history of hemorrhagic disorders (like as hemophilia, von Willebrand s disease, and so forth), poly hydramnius, Large episiotomy, internal diseases (like as Asthma, preeclampsia, cardiac diseases and so forth), etc.

##### Age

From **15 years** old to **45 years** old

##### Gender

Female

## Phase

2

## 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

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice Chancellor for research - Guilan university of medical sciences

##### Street address

Vice Chancellor for research of Guilan university of medical sciences, Namjoo street

##### City

Rasht

##### Postal code

#### Approval date

empty

#### Ethics committee reference number

1694

## Health conditions studied

### 1

#### Description of health condition studied

intrapartum haemorrhage

#### ICD-10 code

O67.8

#### ICD-10 code description

Other intrapartum haemorrhage

## Primary outcomes

### 1

#### Description

Hematocrit decline

#### Timepoint

before delivery twelve hours after that

## Method of measurement

hemoglobin and Hematocrit level

### 2

#### Description

postpartum hemorrhage

#### Timepoint

During delivery, one and twelve hours after that

#### Method of measurement

By using scaled dish, weight of bloody gauzes and cloths

## Secondary outcomes

### 1

#### Description

third part of delivery time

#### Timepoint

During delivery and one hour after that

#### Method of measurement

Measuring of neonatal birth time until the placenta full evacuation

### 2

#### Description

frequency of need for blood transfusion

#### Timepoint

Before delivery and 12 hours after that

#### Method of measurement

More than 10 percent decline in Hb and Hct level, rising of pulse rate

### 3

#### Description

maternal complications frequency

#### Timepoint

One, four and twelve hours after delivery

#### Method of measurement

Questionnaire

### 4

#### Description

uterine Atony

#### Timepoint

During delivery , one, 4 and 12 hours after that

#### Method of measurement

Sever of vaginal bleeding after delivery

## Intervention groups

### 1

#### Description

Intervention group: 400 microgram of sublingual Misoprostol plus 20 ml of distilled water (as placebo)

#### Category

Treatment - Drugs

## 2

### Description

Control group: 20 ml of intravenous Oxytocine plus two tablet of sublingual placebo

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra Hospital, Guilan university of medical sciences

##### Full name of responsible person

##### Street address

Namjoo Street

##### City

Rasht

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research vice chancellorship - Guilan university of medical sciences

##### Full name of responsible person

Dr. Abdolrasol Sobhani

##### Street address

Namjo street

##### City

Rasht

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Research vice chancellorship - Guilan 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

Reproductive Health Research center, Guilan University of Medical Sciences

#### Full name of responsible person

Fereshte Fakoor

#### Position

Assistant professor of Obstetric and Gynecology

#### Other areas of specialty/work

#### Street address

Reproductive Health Research center, Department of Ob & Gyn, Alzahra Hospital, Namjo street

#### City

Rasht

#### Postal code

#### Phone

+98 13 1322 5624

#### Fax

#### Email

fakoor@gums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Reproductive Health Research center, Guilan University of Medical Sciences

#### Full name of responsible person

Fereshte Fakoor

#### Position

Assistant professor of Obstetric and Gynecology

#### Other areas of specialty/work

#### Street address

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#### City

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fakoor@gums.ac.ir

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Reproductive Research Health Center, Guilan University of Medical Sciences

#### Full name of responsible person

Seyede Fatemeh Dalil Heirati

#### Position

Bs in Midwifery

#### Other areas of specialty/work

#### Street address

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#### Fax

#### Email

fatemehdalil@yahoo.com

**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

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

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*