

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Clinical trial of the effects of misoprostol injection compared with oxytocin injection in the umbilical vein in treatment of placenta retaining after delivery

Protocol summary

Summary

Objectives: Determine of the effect of misoprostol and oxytocin treatment of the placenta retaining Designing : Women in labor room who have retained placenta divided into two groups randomly , single-blind, multicenter, Phase 3 of trial Method: women who delivered vaginally in the third phase of labor more than 30 minutes with retained placenta divided into two groups randomly. First group take oxytocin injection (50 units) and second group take misoprostol injection(800 mg). Both injections are done in umbilical vein. During the first and second stages of labor with success, leaving the pair within half an hour after leaving the fetus from the uterus, to obtain written consent from patients to participate in the study Exclusion criteria: Maternal and fetal problems that lead to vaginal delivery is possible. ; Placenta within half an hour after leaving the fetus from the uterus, patient request for exclusion Intervention1: oxytocin 50 units in 30 mL of saline into the umbilical vein Intervention 2: misoprostol injection of 800 mg in 30 mL of saline into the umbilical vein Primary outcomes: the final withdrawal of uterus Secondary outcomes: The Women treated postpartum bleeding and anemia

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102824754N1**
Registration date: **2016-05-10, 1395/02/21**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-10, 1395/02/21

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-05-09, 1395/02/20

Expected recruitment end date

2016-07-10, 1395/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effects of misoprostol injection compared with oxytocin injection in the umbilical vein in treatment of placenta retaining after delivery

Public title

The effect of misoprostol and oxytocin in the treatment of placenta retaining

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: During the first and second stages of

labor with success, leaving the pair within half an hour after leaving the fetus from the uterus, to obtain written consent from patients to participate in the study
Exclusion criteria: Maternal and fetal problems that lead to vaginal delivery is possible. ; Placenta within half an hour after leaving the fetus from the uterus, patient request for exclusion

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Moheb Yas hospital, North Villa St, Karim khan St.

City

Tehran

Postal code

Approval date

2016-05-08, 1395/02/19

Ethics committee reference number

IR.TUMS.REC.1395.2566

Health conditions studied

1

Description of health condition studied

Relation the effects of misoprostol and oxytocin in the treatment of placenta

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Withdrawal time of placenta

Timepoint

30 minutes

Method of measurement

According on minutes

Secondary outcomes

empty

Intervention groups

1

Description

Injection of oxytocin 50 units mixed with 30 mL of saline normal into the umbilical vein

Category

Treatment - Drugs

2

Description

Injection of misoprostol 800 mg mixed with 30 mL of saline normal into the umbilical vein

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Moheb Yas hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Research Deputy

Street address

BLW Keshavarz, Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Tehran 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**

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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*