

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Comparative study of efficacy and complications of two cervical preparations in term and preterm pregnancies

#### Protocol summary

##### Study aim

Comparative study of efficacy and complications of two cervical preparations in term and preterm pregnancies

##### Design

This study is a non-blinded clinical trial. The study population will be all pregnant women referred to the gynecology ward of Imam Reza hospital in Kermanshah. 50 eligible patients will be selected conveniently and randomly assigned to two intervention groups.

##### Settings and conduct

This study will be conducted at Imam Reza hospital of Kermanshah. At the beginning of the study, variables of age, gestational age, body mass index and level of education will be examined for the similarity between the two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Mother age between 18-35 years; No medical diseases such as diabetes, heart disease, pulmonary, renal disease, hypertension and history of hospitalization due to mental illness; Body mass index less than 26 Exclusion criteria: Indication for termination of pregnancy; Use oxytocin before and during the first contraction monitor; Cesarean section for some reason except for stopping delivery or pelvic stenosis.

##### Intervention groups

In the first intervention group, oxytocin will be injected simultaneously with the balloon inserted at the appropriate position. In the second intervention group, oxytocin will be injected after balloon withdrawal. In both groups, injections will be started at 2 mu/min oxytocin and continue every 30 minutes with 2 mu/min until delivery.

##### Main outcome variables

Postpartum hemorrhage

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20130812014333N137**

Registration date: **2020-02-05, 1398/11/16**

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

Last update: **2020-02-05, 1398/11/16**

Update count: **0**

##### Registration date

2020-02-05, 1398/11/16

#### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

fforoughi@kums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

##### Expected recruitment start date

2020-01-15, 1398/10/25

##### Expected recruitment end date

2020-06-14, 1399/03/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Comparative study of efficacy and complications of two cervical preparations in term and preterm pregnancies

**Public title**

Comparative study of efficacy and complications of two cervical preparations in term and preterm pregnancies

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Mother age between 18-35 years Lack of medical diseases such as diabetes, heart disease, pulmonary, renal disease, hypertension and history of hospitalization due to mental illness Body mass index less than 26

**Exclusion criteria:**

Indication for termination of pregnancy Use oxytocin before and during the first contraction monitor Cesarean section for some reason except stopping delivery or pelvic stenosis

**Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using the random number table, patients are divided into two groups of 53. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group.

**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 Kermanshah University of Medical Sciences

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2019-11-26, 1398/09/05

**Ethics committee reference number**

IR.KUMS.REC.1398.939

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

Pregnancy

**ICD-10 code**

Z34

**ICD-10 code description**

Encounter for supervision of normal pregnancy

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

Postpartum hemorrhage

**Timepoint**

After the end of the study

**Method of measurement**

Based on patient records

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the first intervention group, oxytocin will be injected simultaneously with the balloon inserted at the appropriate position. Injections will be started at 2 mu/min oxytocin and continue every 30 minutes with 2 mu/min until delivery.

**Category**

Treatment - Drugs

**2****Description**

In the second intervention group, oxytocin will be injected after balloon withdrawal. Injections will be started at 2 mu/min oxytocin and continue every 30 minutes with 2 mu/min until delivery.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Emam Reza Hospital

**Full name of responsible person**

Maryam Fatahi

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

rezaei120alireza@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Farid Najafi

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3836 0014

**Email**

fnajafi@kums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Maryam Fatahi

**Position**

Resident of Obstetrics and Gynecology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

rezaei120alireza@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Maryam Zanganeh

**Position**

Member of Kermanshah University of Medical Sciences

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

mzangeneh@kums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Maryam Fatahi

**Position**

Resident of Obstetrics and Gynecology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Email**

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The main outcomes of the study will be shared.

**When the data will become available and for how long**

3 months

**To whom data/document is available**

If requested, results will be made available to other academic researchers

**Under which criteria data/document could be used**

Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

**What processes are involved for a request to access data/document**

In a 15-day period, the documents will be sent e-mail

**Comments**