# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## A comparative study on the effect of vaginal misoprostol usage with the combination of evening primrose and vaginal misoprostol in the treatment of missed abortion.

## Protocol summary

**Study aim**
A comparative study on the effect of vaginal misoprostol usage with the combination of evening primrose and vaginal misoprostol in the treatment of missed abortion.

**Design**
140 Pregnant women with missed abortion in intervention and control groups, Clinical trial ,Randomized, It is not possible to be blind

**Settings and conduct**
The study population was all pregnant women referred to Niknafs Rafsanjan Hospital and under 20 weeks of gestation with the diagnosis of missed abortion and is randomly assigned to one of 2 intervention or control groups.The sample size was estimated based on statistical calculations of 140 people (70 in each group).The intervention group is recommended to use two vaginal primerose capsules of 1000 mg at bedtime. As placebo is not effective in controlling cervical readiness, there is no need for placebo. After referral, the next morning, misoprostol is vaginally implanted and hospitalized by the emergency midwife. After studying the case file, the researcher extracts the necessary information from the file and enters the checklist.

**Participants/Inclusion and exclusion criteria**
The inclusion criteria: All of women with a diagnosis of missed abortion;inclination to participate in the study; selection of Niknafs hospital for abortion induction.The exclusion criteria:vaginal bleeding; diseases associated with disorders Hemorrhagic agents,anticoagulant drugs, patients with history of psychiatric disorders in the phenothiazine category,and epilepsy patients

**Intervention groups**
Intervention group: The vaginal usage of two1000mg Primrose capsules at the night before hospitalization.Control group:No placebo prescription needed.

**Main outcome variables**
Dosage of Misoprostol, Disposal time of pregnancy products, Severity of the bleeding

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20160308026971N8**
Registration date: **2020-02-15, 1398/11/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-15, 1398/11/26**
Update count: **0**

**Registration date**
2020-02-15, 1398/11/26

**Registrant information**

**Name**
Marzeyeh Loripoor

**Name of organization / entity**
Rafsanjan University Medical Science

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-11-12, 1398/08/21

**Expected recruitment end date**
2020-11-11, 1399/08/21

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
A comparative study on the effect of vaginal misoprostol usage with the combination of evening primrose and vaginal misoprostol in the treatment of missed abortion.

**Public title**
The effect of evening primrose in the treatment of missed abortion process.
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
All of women with a diagnosis of missed abortion Inclination to participate in the study Selection of Niknafs hospital for abortion induction
**Exclusion criteria:**
Vaginal bleeding diseases associated with disorders Hemorrhagic agents, anticoagulant drugs, Patients with history of psychiatric disorders in the phenothiazine category, and epilepsy patients
**Age**
No age limit
**Gender**
Female

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **140**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
This randomization method is assigned to intervention group 1 and control group 2 and the cards with numbers 1 and 2 are written. Study subjects remove one of these cards and fall into one of the groups.
**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 Rafsanjan University of Medical Science
**Street address**
Central department of Rafsanjan University Medical Science،immam Ali Street
**City**
Rafsanjan
**Province**
Kerman
**Postal code**
7717932777
**Approval date**
2019-11-11, 1398/08/20
**Ethics committee reference number**
IR.RUMS.REC.1398.146

## Health conditions studied

### 1

**Description of health condition studied**
Missed abortion
**ICD-10 code**
O02.1
**ICD-10 code description**
Missed abortion

## Primary outcomes

### 1

**Description**
Dosage of misoprostol
**Timepoint**
After the abortion is complete
**Method of measurement**
Information recorded in the file

### 2

**Description**
Disposal time of pregnancy products
**Timepoint**
After the abortion is complete
**Method of measurement**
Information recorded in the file

### 3

**Description**
The severity of the bleeding
**Timepoint**
After the abortion is complete
**Method of measurement**
Information recorded in the file

## Secondary outcomes

### 1

**Description**
Pain rate
**Timepoint**

During of the hospitalization

**Method of measurement**

Visual analogue scale

**2**

**Description**

Number of days of hospitalization

**Timepoint**

After the patient is discharged

**Method of measurement**

The information recorded in the file

**3**

**Description**

Curettage

**Timepoint**

During of the hospitalization

**Method of measurement**

The information recorded in the file

## Intervention groups

**1**

**Description**

Intervention group: In addition to routine treatment of missed abortion with vaginal misoprostol, Two 1000 mg primerose capsules made by Barij essential company,10 pm before hospitalization,Vaginal

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Routine treatment of missed abortion with vaginal misoprostol

**Category**

N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

NickNaf maternity hospital Rafsanjan

**Full name of responsible person**

Mozhgan Mahmoodi Nasab

**Street address**

Shohada Ave.

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Dr. Ali Shamsizadeh

**Street address**

Imam Ali Blvd., Dept. of Research & Technology,Central Office of Rafsanjan University of Medical Sciences,

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alishamsy@gmail.com

**Web page address**

http://vcrt.rums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Rafsanjan 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**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Marzeyeh Loripoor

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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## Person responsible for updating data

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**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There is not more information
**Study Protocol**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available