

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The comparison of the efficacy of oral castor oil with vaginally misoprostol and vaginally misoprostol alone in the treatment of missed abortion

#### Protocol summary

##### Summary

The goal of research is to compare the efficacy of oral castor oil with vaginally misoprostol and vaginally misoprostol alone in the treatment of missed abortion .The method of study is randomized ,triple blind, placebo controlled clinical trial. Study population are pregnant women with missed abortion referred to Taleghani Hospital. Inclusion criteria: missed abortion according to sonography exclusion criteria: severe anemia; sensitivity to prostaglandine : coagulopathy ;acute liver disease; heart disease.72 subjects are randomly divided in 2 groups (intervention and control). Intervention group receive misoprostol 800 microgram vaginally plus castor oil 60 ml orally. Control group receive misoprostol 800 microgram vaginally plus placebo 60 ml orally. If it does not response to primary dose, mioprostol would be repeated up to three times with 24 hours interval. Primary outcome is cervical dilatation

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201403244686N11**  
Registration date: **2014-04-13, 1393/01/24**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-04-13, 1393/01/24

##### Registrant information

##### Name

Mehri Jamilian

##### Name of organization / entity

School of Medicine, Arak University of Medical

Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 1278 0660

##### Email address

mjamilian@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice president of education and research ,Arak University of Medical Sciences

##### Expected recruitment start date

2014-03-30, 1393/01/10

##### Expected recruitment end date

2014-07-01, 1393/04/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of the efficacy of oral castor oil with vaginally misoprostol and vaginally misoprostol alone in the treatment of missed abortion

##### Public title

The comparison of the efficacy of oral castor oil with vaginally misoprostol and vaginally misoprostol alone in the treatment of missed abortion

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criterion: missed abortion according sonography . Exclusion criteria: sever anemia; sensitivity to prostaglandine; coagulopathy; acute liver disease;

heart disease.

**Age**  
From **18 years** old to **45 years** old

**Gender**  
Female

**Phase**  
2

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **72**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**

**Name of ethics committee**  
Arak University of Medical Sciences

**Street address**  
Basij Square

**City**  
Arak

**Postal code**  
3816149369

**Approval date**  
2014-02-22, 1392/12/03

**Ethics committee reference number**  
18-158-92

## Health conditions studied

1

**Description of health condition studied**  
treatment of missed abortion

**ICD-10 code**  
O02.1

**ICD-10 code description**  
Missed abortion Early fetal death with retention of dead fetus

## Primary outcomes

1

**Description**  
treatment of missed abortion

**Timepoint**  
before intervention and four hour after intervention

**Method of measurement**  
vaginal exam

## Secondary outcomes

1

**Description**  
drug side effects

**Timepoint**  
before intervention and four hour after intervention

**Method of measurement**  
vaginal exam

## Intervention groups

1

**Description**  
Intervention group receive misoprostol 800 microgram vaginally plus castor oil 60 ml orally. If it does not response to primary dose, mioprostol would be repeated up to three times with 24 hours interval.

**Category**  
Treatment - Drugs

2

**Description**  
Control group receive misoprostol 800 microgram vaginally plus placebo 60 ml orally. If it does not response to primary dose, mioprostol would be repeated up to three times with 24 hours interval.

**Category**  
Treatment - Drugs

## Recruitment centers

1

**Recruitment center**

**Name of recruitment center**  
Arak.University of Medical Sciences

**Full name of responsible person**  
Mehri Jamilian

**Street address**  
Taleghani Hospital

**City**  
Arak

## Sponsors / Funding sources

1

**Sponsor**  
**Name of organization / entity**

Arak University of Medical Sciences  
**Full name of responsible person**  
 Dr.Ali Asghar Yaghobi  
**Street address**  
 Basij Square  
**City**  
 Arak  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
 Yes  
**Title of funding source**  
 Arak 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**  
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 Arak University of Medical Sciences  
**Full name of responsible person**  
 Mehri Jamilian  
**Position**  
 Board of Obstetric and Gynecology ,Assistant  
 Professor  
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## 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*