

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 two 1000mg 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)

Phone

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Email address

m.loripoor@rums.ac.ir

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

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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

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

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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 scientific inquiries

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Marzeyeh Loripoor

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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