

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of misoprostol with isosorbide mononitrate on the induction of first-trimester abortion

Protocol summary

Study aim

The effect of misoprostol with isosorbide mononitrate on the induction of first-trimester abortion

Design

This study is a one-blinded clinical trial. The study population will be all less than 13 weeks pregnant who are candidates for termination of pregnancy referred to Imam Reza Hospital of Kermanshah. 54 eligible patients will be selected conveniently and randomly assigned to two intervention and control groups.

Settings and conduct

This study that will be conducted in Imam Reza hospital of Kermanshah city is a one-blinded one that the data analyzer was kept blind to the allocation of study groups. At baseline, both groups were matched for age, gestational age, parity, gravidity, height, weight (BMI), and previous abortion.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Nullipara and multipara to 5 Parity and singleton women; No history of previous cesarean section and uterine surgery; Exclusion criteria: Women with open cervix and contraindication for isosorbide mononitrate (IMN); Women with significant heart disease or anemia

Intervention groups

In the intervention group, 40mg isosorbide mononitrate tablets will be placed in the posterior fornix. Then 4 hours later 800mcg of misoprostol, equivalent to four 200mcg tablets (manufactured by Aria Pharmaceuticals), in a single dose of the saline-will embedded posterior fornix. In the control group, 40 mg vitamin B6 (manufactured by Galinus) will be implanted in the vagina in the posterior fornix b then 4 hours later 800 mcg of misoprostol, equivalent to four 200 mg mcg tablets (manufactured by Aria) in a single dose of saline will embedded posterior fornix.

Main outcome variables

Time of cervical opening from induction onset, time of the secretion of pregnancy products from the onset of

induction, complete abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N138**

Registration date: **2020-02-14, 1398/11/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-14, 1398/11/25**

Update count: **0**

Registration date

2020-02-14, 1398/11/25

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

2020-02-14, 1398/11/25

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of misoprostol with isosorbide mononitrate on the induction of first-trimester abortion

Public title

The effect of misoprostol with isosorbide mononitrate on the induction of first-trimester abortion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Nullipara and multipara to 5 Parity and singleton women
No history of previous cesarean section and uterine surgery

Exclusion criteria:

Women with the open cervix and contraindication for isosorbide mononitrate (IMN) Women with significant heart disease or anemia

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: 54

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table, patients are divided into two groups of 27. 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)

Single blinded

Blinding description

In this study, the data analyzer was kept blind to the allocation of study groups

Placebo

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

2019-12-17, 1398/09/26

Ethics committee reference number

IR.KUMS.REC.1398.1051

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

Therapeutic Abortion

ICD-10 code

O04

ICD-10 code description

Therapeutic/Medical Abortion (termination of pregnancy)

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

Time of cervical opening from induction onset

Timepoint

24 hours after the end of the study

Method of measurement

Doctor Observation

2**Description**

Secretion time of pregnancy products from onset of induction

Timepoint

24 hours after the end of the study

Method of measurement

Doctor Observation

3**Description**

Complete abortion

Timepoint

24 hours after the end of the study

Method of measurement

Doctor Observation

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, 40mg isosorbide mononitrate tablets will be placed in the posterior fornix. Then 4 hours later 800mcg of misoprostol, equivalent to four 200mcg tablets (manufactured by Aria Pharmaceuticals), in a single dose of the saline-will embedded posterior fornix.

Category

Treatment - Other

2

Description

In the control group, 40 mg vitamin B6 (manufactured by Galinus) will be implanted in the vagina in the posterior fornix b then 4 hours later 800 mcg of misoprostol, equivalent to four 200 mg mcg tablets (manufactured by Aria) in a single dose of saline will embedded posterior fornix.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Elham Movahedi Aliabadi

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

Elham_movahedi@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

Vice chancellor for research of 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

Elham Movahedi Aliabadi

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

Elham_movahedi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Anisodoleh Nankali
Position
Member of Kermanshah University of Medical Sciences
Latest degree
Specialist
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
anankali@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
- Elham Movahedi Aliabadi
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
Elham_movahedi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

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

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