Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 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)

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+98 83 1821 4653

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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

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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