Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness and side effects of different ways of misoprostol Prescribed in the termination of the second trimester of pregnancy

Protocol summary

Summary

This study will be conducted with aim to Comparative evaluation of the effectiveness and side effects of different ways of misoprostol Prescribed in the termination of the second trimester of pregnancy. This study is a non blinded clinical trial. The study population will be consisted of pregnant women at 22-13 weeks of pregnancy that due to intrauterine death or congenital anomalies are candidates for termination of pregnancy, that 180 persons in available method is selected and randomly will be assigned to three groups. In all three groups the patients' vital signs will be recorded. In the first group misoprostol 400 mcg is selected that in every 4 hours up to 5 doses will be Prescribed in the form of vaginally. In the second group misoprostol 400 mcg is selected that in every 4 hours up to 5 doses in the form of orally will be Prescribed. In the thired group misoprostol 400 mcg is selected that in every 4 hours up to 5 doses will be Prescribed sublingual. Vital signs and adverse effects in beginning of each dose (hour 1) and 4 hours after Prescribe of each dose in patients will be monitored. Then the interval between Prescrition of the first dose of misoprostol and discharge of pregnancy products will be recorded for each patient. In this study routinely ,for all patients curettage is performed in the operating room and patients' hemoglobin also will be control 6 hours after curettage. Inclusion criteria: singleton pregnancy;gestational age 13 to 22 with an indication for termination of pregnancy in medical procedures; Chorioamnionitis. Exclusion criteria: patients with a history of caesarean section; mother serious systemic and chronic disease , cardiovascular, renal diseases ; known sensitivity to prostaglandins and coagulopathy; uncontrolled seizure disorders; hemolytic disease

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015123014333N47**
Registration date: **2016-01-17, 1394/10/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-01-17, 1394/10/27

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

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-05-30, 1395/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness and side effects of different ways of misoprostol Prescribed in the termination of the second trimester of pregnancy

Public title
Comparative evaluation of the effectiveness and side effects of different ways of misoprostol Prescribed in the termination of the second trimester of pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: singleton pregnancy;gestational age 13 to 22 with an indication for termination of pregnancy in medical procedures; Chorioamnionitis. Exclusion criteria: patients with a history of caesarean section; mother serious systemic and chronic disease , cardiovascular, renal diseases ; known sensitivity to prostaglandins and coagulopathy; uncontrolled seizure disorders; hemolytic disease

Age
From **3 months** old to **6 months** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Committee Moral, Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City
Kermanshah

Postal code

Approval date
2015-12-01, 1394/09/10

Ethics committee reference number
Kums.Rec.1394.217

Health conditions studied

1

Description of health condition studied
Medical abortion

ICD-10 code
O04

ICD-10 code description
Medical abortion

Primary outcomes

1

Description
Ague

Timepoint
Baseline and 4 hours after drug administration

Method of measurement
By asking of patient

2

Description
Abdominal pain

Timepoint
Baseline and 4 hours after drug administration

Method of measurement
By asking of patient

3

Description
Nausea

Timepoint
Baseline and 4 hours after drug administration

Method of measurement
By asking of patient

4

Description
Vaginal bleeding

Timepoint
Baseline and 4 hours after drug administration

Method of measurement
By asking of patient and doctor observation

5

Description
Vomiting

Timepoint

Baseline and 4 hours after drug administration

Method of measurement

By asking of patient

6

Description

During the induction of abortion

Timepoint

From the intervention to discharge pregnancy products

Method of measurement

Based on clinical signs and doctor observation

Secondary outcomes

empty

Intervention groups

1

Description

In the first group misoprostol 400 mcg is selected that in every 4 hours up to 5 doses will be Prescribed in the form of vaginally.Vital signs and adverse effects in beginning of each dose (hour 1) and 4 hours after Prescribe of each dose in patients will be monitored. Then the interval between Prescrition of the first dose of misoprostol and discharge of pregnancy products will be recorded for each patient

Category

Treatment - Drugs

2

Description

In the second group misoprostol 400 mcg is selected that in every 4 hours up to 5 doses in the form of orally will be Prescribed. Vital signs and adverse effects in beginning of each dose (hour 1) and 4 hours after Prescribe of each dose in patients will be monitored. Then the interval between Prescrition of the first dose of misoprostol and discharge of pregnancy products will be recorded for each patient

Category

Treatment - Drugs

3

Description

In the thired group misoprostol 400 mcg is selected that in every 4 hours up to 5 doses will be Prescribed sublingual. Vital signs and adverse effects in beginning of each dose (hour 1) and 4 hours after Prescribe of each dose in patients will be monitored. Then the interval between Prescrition of the first dose of misoprostol and discharge of pregnancy products will be recorded for each patient

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Ronak Rezaei

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Anisodole Nankali

Position
Obstetricians
Other areas of specialty/work
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Postal code
Phone
+98 83 3427 6301
Fax
Email
anankali@kums.ac.ir
Web page address

Person responsible for updating data

Contact

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