Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Comparison of Misoprostol plus Isosorbide Mono Nitrate and Misoprostol plus placebo at the end of second trimester pregnancy.

Protocol summary

Study aim

The aim of this study is to compare Misoprostol, Isosorbide Mono Nitrate and Misoprostol, Placebo at the end of the second trimester of pregnancy.

Design

This study is a prospective, single-blind clinical trial on singleton pregnant women, with gestational age 22-13 weeks, undergoing termination of pregnancy. 54 patients divided into two groups and intervention and placebo ,A code was allocated to each one of them

Settings and conduct

The location of the study is Imam Reza Hospital in Kermanshah. After describing the conditions of the plan for patients, If patients complete Informed consent. They are divided into two intervention groups (Misoprostol + Isosorbide Mononitrate) and the Placebo group (Misoprostol + Placebo)

Participants/Inclusion and exclusion criteria

Inclusion criteria include nulliparous and multiparous women to parity 5. Exclusion criteria include multifetal pregnancy, contra indication of Isosorbide mono nitrate (IMN) and contra indication of misoprostol .

Intervention groups

Patients(54 cases) were randomly divided into two groups: A (Misoprostol + Placebo) and B (Misoprostol + Isosorbide Mono Nitrate).In group A, vitamin B6, 40 mg (Jalinoos Company), is inserted into the vagina in posterior fornix, and 4 hours later, Misoprostol 400mcg, equivalent to two 200mcg tablets (aria Company) stained with saline will be insertedIn group B Isosorbide Mononitrate 40 mg, is inserted into the vagina in posterior fornix, and 4 hours later, Misoprostol 400mcg stained with saline will be inserted. In the event of treatment failure (failure to pass the gestational product within 24 hours), the second course of treatment will be done.

Main outcome variables

Failure to pass the gestational product within 24 hours, abdominal pain, spotting, nausea, vomiting, diarrhea, headache, dizziness, palpitation and fever

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100525004025N5**
Registration date: **2017-12-15, 1396/09/24**
Registration timing: **retrospective**

Last update: **2017-12-15, 1396/09/24**
Update count: **0**

Registration date

2017-12-15, 1396/09/24

Registrant information

Name

Anisodowleh Nankali

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Kermanshah university of medical sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Misoprostol plus Isosorbide Mono Nitrate and Misoprostol plus placebo at the end of second trimester pregnancy.

Public title

Effect of misoprostol plus isosorbide mononitrate and misoprostol plus placebo in induction of second trimester abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age 22-13 weeks can be a condition for entering the study. nulliparous Can be a condition for entering the study. Multiparous to parity 5 Can be a condition for entering the study. singleton pregnancy can be a condition for entering the study.

Exclusion criteria:

Women with contra indication of misoprostol (active Cardiac-pulmonary disease, Placenta Previa, history of 2 or more previous cesarean section, or history of major uterine surgeries such as myomectomy and uterine reconstruction surgery)Conditions for not admitting to study. Women with contraindication of Isosorbide mono nitrate (IMN) (sensitivity to nitrates, hypotension, hypovolemia, heart disease, significant anemia Hb below 7 gr / dl and closed angle glaucoma)Conditions for not admitting to study.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

If patients complete Informed consent, they are divided into two intervention groups (Misoprostol +Isosorbide Mononitrate) and the placebo group (Misoprostol + Placebo) . Patients do not know the type of drug they receive

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Kermanshah, Nursing Blvd, Sorkhe Lyzheh, Imam Reza Teaching Hospital,

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Province

Kermanshah

Postal code

15333-67144

Approval date

2016-12-14, 1395/09/24

Ethics committee reference number

kums.rec.1395.532

Health conditions studied

1

Description of health condition studied

Termination of pregnancy

ICD-10 code

XV

ICD-10 code description

Pregnancy with abortive outcome

Primary outcomes

1

Description

The abortion rate is 12 hours

Timepoint

12 hours later intervention

Method of measurement

View the disposal of pregnancy products

2

Description

The abortion rate is 24-12 hours

Timepoint

Abortion after 12 hours to 24 hours of intervention

Method of measurement

View the disposal of pregnancy products

3

Description

Abortion rate after 24 hours

Timepoint

In the 24th hour of the intervention

Method of measurement
View the disposal of pregnancy products

Secondary outcomes

1

Description
Nausea
Timepoint
Every 4 hours after intervention until the Disposal of pregnancy products
Method of measurement
See Symptoms of the patient

2

Description
vomiting
Timepoint
Every 4 hours after intervention until the disposal of pregnancy products
Method of measurement
See Symptoms of the patient

3

Description
Diarrhea
Timepoint
Every 4 hours after intervention until the disposal of pregnancy products
Method of measurement
See Symptoms of the patient

4

Description
Fever and chills
Timepoint
Every 4 hours after intervention until the disposal of pregnancy products
Method of measurement
See Symptoms of the patient

5

Description
Headache
Timepoint
Every 4 hours after intervention until the disposal of pregnancy products
Method of measurement
See Symptoms of the patient

6

Description
heart beat
Timepoint
Every 4 hours after intervention until the disposal of pregnancy products
Method of measurement
See Symptoms of the patient

7

Description
Confusion
Timepoint
Every 4 hours after intervention until the disposal of pregnancy products
Method of measurement
See Symptoms of the patient

Intervention groups

1

Description
In group A(control), vitamin B6, 40 mg, is inserted into the vagina in posterior fornix, and 4 hours later, misoprostol 400mcg, equivalent to two 200mcg tablets stained with saline will be inserted .
Category
Placebo

2

Description
In group B(case) Isosorbide Mononitrate 40 mg, is inserted into the vagina in posterior fornix, and 4 hours later, Misoprostol 400mcg stained with saline will be inserted.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Teaching Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number
10421600

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

Title of funding source
Research deputy 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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

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