

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Scientific Title :Comparison the effect of vaginal and sublingual Misoprostol in successful termination of pregnancy in 12-24 weeks pregnant women admitted in Alzahra Hospital - Rasht in 2011-2012

Protocol summary

Summary

The aim of this study is comparison of vaginal versus sublingual Misoprostol in successful termination of pregnancy. This study will be done on 268 pregnant women admitted in Alzahra hospital-Rasht 2011-2012. Inclusion criteria are 12-24 weeks single pregnancy confirmed with certain LMP and < 20 weeks sonography. Exclusion criteria is Known sensitivity to prostaglandins, previous caesarian section, vaginal bleeding and placenta previa, Parity > 3. Women randomly will be divided in two groups. One group will be treated with sublingual misoprostol and vaginal placebo and another group will be treated with vaginal misoprostol and sublingual placebo. The doses are given each 3 hours to 24 hours and if pregnancy isn't terminated, another doses should be continued each 3 hours to 48 hours and then if pregnancy still isn't terminated within 48 hours, other methods will be used such as high dose oxytocin or historotomy. Vital signs and side effects (such as nausea, headache, breast tenderness, diarrhea, chilling, fever frequency of needing to analgesics, vomiting) will be control every 3 hours and register. The main outcome is the time interval between drug using to pregnancy termination and second outcome is abortion within 24 hours, abortion within 48 hours, comparing the pain onset after drug using in two groups and comparing the side effects. Data will be evaluated with statistical methods. The time interval of drug therapy to pregnancy termination will be compare in both groups and data will be evaluated with statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106213485N3**
Registration date: **2011-08-15, 1390/05/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-08-15, 1390/05/24

Registrant information

Name

Forozan Milani

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2012-08-22, 1391/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Scientific Title :Comparison the effect of vaginal and sublingual Misoprostol in successful termination of

pregnancy in 12-24 weeks pregnant women admitted in Alzahra Hospital - Rasht in 2011-2012

Public title

Comparison the effect of vaginal versus sublingual misoprostol in termination of pregnancy of 12-24 weeks

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : 12-24 weeks single pregnancy confirmed with certain LMP and > 20 weeks sonography
Exclusion criteria : Known sensitivity to prostaglandins (questions such as skin rash, wheels, dyspnea, cough, chest pain, blurred vision); previous caesarian section; Vaginal bleeding; placenta previa; Parity > 3

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **268**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee Guilan University of Medical Sciences

Street address

Vice Chancellor for research, Guilan University of Medical Sciences, Melat st, Namjoo Ave

City

Rasht

Postal code

Approval date

2011-05-28, 1390/03/07

Ethics committee reference number

190013606

Health conditions studied

1

Description of health condition studied

Pregnancy, childbirth and the puerperium

ICD-10 code

O04

ICD-10 code description

Medical abortion

Primary outcomes

1

Description

Comparing the effect of vaginal versus sublingual misoprostol in termination of pregnancy

Timepoint

Each 3 hours to 24 hours then if the pregnancy isn't terminated misoprostol will be continued each 3 hours to 48 hours

Method of measurement

Observation of fetus expulsion

Secondary outcomes

1

Description

Determining the relative frequency of Abortion within 48 hours after using vaginal misoprostol

Timepoint

Each 3 hours to 48 hours after using sublingual misoprostol

Method of measurement

Measuring the time interval between using sublingual misoprostol to abortion

2

Description

Comparing the relative frequency of abortion within 24 hours in vaginal and sublingual misoprostol using

Timepoint

Each 3 hours to 24 hours

Method of measurement

Measuring the time interval between using vaginal misoprostol and sublingual misoprostol to abortion

3

Description

Determining the relative frequency of Abortion within 24 hours after using vaginal misoprostol

Timepoint

Each 3 hours to 24 hours

Method of measurement

Measuring the time interval between using vaginal misoprostol to abortion

4

Description

Determining the relative frequency of Abortion within 24

hours after using sublingual misoprostol

Timepoint

Each 3 hours to 24 hours

Method of measurement

Measuring the time interval between using sublingual misoprostol to abortion

5

Description

Determining the relative frequency of Abortion within 48 hours after using vaginal misoprostol

Timepoint

Each 3 hours to 48 hours after using sublingual misoprostol

Method of measurement

Measuring the time interval between using sublingual misoprostol to abortion

6

Description

Comparing the relative frequency of abortion within 48 hours after using vaginal and sublingual misoprostol

Timepoint

3 hours to 48 hours after using vaginal and sublingual misoprostol

Method of measurement

Measuring the time interval between using vaginal and sublingual misoprostol to abortion

7

Description

Measuring the time interval after using vaginal misoprostol to pain onset

Timepoint

Each 3 hours

Method of measurement

Pain visual scale

8

Description

Measuring the time interval after using sublingual misoprostol to pain onset

Timepoint

Each 3 hours

Method of measurement

Pain visual scale

9

Description

Comparing the time interval between use vaginal and sublingual misoprostol and pain onset

Timepoint

Each 3 hours

Method of measurement

Pain visual scale

10

Description

Determining the frequency of side effect (nausea, dizziness, headache, diarrhea, vomiting, chilling fever) in vaginal misoprostol group

Timepoint

Each 3 hours

Method of measurement

Nausea, dizziness, headache, chilling, diarrhea based on patient's word, Vomiting: observing expulsion of content with pressure through upper gastro intestinal system, Fever: detection body temprature with termometer

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Description

Determining the frequency of side effect (nausea, dizziness, headache, diarrhea, vomiting, chilling fever) in sublingual misoprostol group

Timepoint

Each 3 hours

Method of measurement

Nausea, dizziness, headache, chilling, diarrhea based on patient's word, Vomiting: observing expulsion of content with pressure through upper gastro intestinal system, Fever: detection body temperature with termometer

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Description

Comparing the frequency of side effect (nausea, dizziness, headache, diarrhea, vomiting, chilling fever) in vaginal and Sublingual misoprostol group

Timepoint

Each 3 hours

Method of measurement

Nausea, dizziness, headache, chilling, diarrhea based on patient's word, Vomiting: observing expulsion of content with pressure through upper gastro intestinal system, Fever: detection body temperature with termometer

13

Description

Determining the frequency of needing to analgesics in sublingual misoprostol group

Timepoint

Each 3 hours

Method of measurement

Measuring analgesics doses

14

Description

Determining the frequency of needing to analgesics in vaginal misoprostol group

Timepoint

Each 3 hours

Method of measurement

Measuring analgesics doses

15

Description

Comparing the frequency of needing to analgesics in vaginal and misoprostol group

Timepoint

Each 3 hours

Method of measurement

Measuring analgesics doses

16

Description

Determining the frequency of breast tenderness in sublingual misoprostol group

Timepoint

Each 3 hours

Method of measurement

Question about pain if positive then breast examination

17

Description

Determining the frequency of breast tenderness in vaginal misoprostol group

Timepoint

Each 3 hours

Method of measurement

Question about pain if positive then breast examination

18

Description

Comparing the frequency of breast tenderness in vaginal and sublingual misoprostol group

Timepoint

Each 3 hours

Method of measurement

Question about pain if positive then breast examination

19

Description

Determining the average doses of misoprostol using for pregnancy termination in sublingual misoprostol group

Timepoint

From using misoprostol to pregnancy termination

Method of measurement

Determining the average doses of sublingual misoprostol needed for pregnancy termination

20

Description

Determining the average doses of misoprostol using for pregnancy termination in vaginal misoprostol group

Timepoint

From using misoprostol to pregnancy termination

Method of measurement

Determining the average doses of vaginal misoprostol needed for pregnancy termination

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Description

Comparing the average doses of misoprostol using for pregnancy termination in vaginal and sublingual misoprostol group

Timepoint

From using misoprostol to pregnancy termination

Method of measurement

Determining the average doses of vaginal and sublingual misoprostol needed for pregnancy termination

Intervention groups

1

Description

Vaginal misoprostol + sublingual placebo tablet. Tablet misoprostol is prescribe in the form vaginal, is a prostaglandin group, 200 micrograms. Interval of prescription is every 3 hours to 24 hours and then if pregnancy isnt terminated should be continued to 48 hours.

Category

Treatment - Drugs

2

Description

Sublingual misoprostol + vaginal placebo . Tablet misoprostol tablet is prescribe in the form sublingual , prostaglandin group, 200 microgram. Interval of prescription is every 3 hours to 24 hours and then if pregnancy isnt terminated should be continued to 48 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital, Guilan University of Medical Sciences

Full name of responsible person

Dr Forozan milani

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Dr. Abdolrasol Sobhani

Street address

Mellat St., Namjoo Ave.

City

Rasht

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, Guilan 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****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Dr Forozan Milani

Position

Obstetrics Gynecologist, Fellowship prenatalogy

Other areas of specialty/work**Street address**

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City

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Web page address**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