Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of The effect between two dose (800 µg/day & 400 µg/6) of vaginal misoprostol in the termination of first-trimester pregnancy: a double-blinded randomized trial

Protocol summary

Summary

Background and aim: a higher dose of misoprostol may increase its efficacy on the termination of pregnancy, we compared the impact of 400 µg every 6 hours daily with 800 µg daily of vaginal misoprostol for termination of early pregnancy. Methods and materials: in this randomized clinical trial 90 pregnant women with gestational age less than 96 days will be randomized to receive vaginal misoprostol either the 400 µg every 6 hours (group A) or 800 µg once a day (group B) for three days, then, success of abortion and complication of these methods were compared with each others. The criteria for enrollment are singleton pregnancy, indication for pregnancy termination due to either fetal or maternal causes and gestational age lower than 96 days and no previous misoprostol consuming.The exclusion criteria are any sign or symptom of threatened or spontaneous abortion before therapy such as bleeding, any degree of dilatation in cervix or uterine regular contractions before drug administration.

General information

Acronym

misoprostol in pregnancy

IRCT registration information

IRCT registration number: **IRCT2017040633255N1**
Registration date: **2017-06-25, 1396/04/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-25, 1396/04/04

Registrant information

Name

Donya Khosravi

Name of organization / entity

Imam Hossein Hospital-ShahidBeheshti Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 7754 3634

Email address

donyakhosravi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-03-29, 1394/01/09

Expected recruitment end date

2016-01-29, 1394/11/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The effect between two dose (800 µg/day & 400 µg/6) of vaginal misoprostol in the termination of first-trimester pregnancy: a double-blinded randomized trial

Public title

Comparison of The effect between two dose (800 µg/day & 400 µg/6) of vaginal misoprostol in the termination of first-trimester pregnancy: a double-blinded randomized trial

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: singleton pregnancy; indication for pregnancy termination due to either fetal or maternal causes and gestational age lower than 96 days; no previous misoprostol consuming. exclusion criteria: any sign or symptom of threatened; spontaneous abortion before therapy such as bleeding; any degree of dilatation in cervix or uterine regular contractions before drug administration.

Age
From **12 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

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

1

Registry name
NA

Secondary trial Id
NA

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethic committee of Shahid Beheshti University of Medical Sciences

Street address
Chamran highway Tabnak st near Taleghani Hospital

City
Tehran

Postal code

Approval date
2015-03-14, 1393/12/23

Ethics committee reference number
sbmu.rec.1393.553

Health conditions studied

1

Description of health condition studied
need to medical abortion due to maternal indications or missed abortion and blighted ovum

ICD-10 code
O04.1

ICD-10 code description
Medical abortion : incomplete, complicated by delayed or excessive haemorrhage

Primary outcomes

1

Description
Complete abortion without needing to a surgery

Timepoint
once

Method of measurement
observed by the obstetrician

Secondary outcomes

1

Description
persistent Bleeding

Timepoint
once

Method of measurement
observed by obstetricans

Intervention groups

1

Description
Intervention group: patients receiving vaginal misoprostol 400 µg every 6 hours up to three days

Category
Treatment - Drugs

2

Description
control group: the other group is patients receiving vaginal misoprostol 800 µg daily up to three days

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hossein Hospital

Full name of responsible person

Dr. Donya Khosravi

Street address

ShahidMadani st after Imam Ali highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice chancellor for research of Shahid Beheshti University of Medical Sciences

Full name of responsible person

research management

Street address

Chamran highway Tabnak st near Taleghani Hospital

City

Tehran

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 of Shahid Beheshti 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

Imam Hossein Hospital

Full name of responsible person

Dr.Donya Khosravi

Position

Academic board

Other areas of specialty/work

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Position

Gynecologist and obstetrician

Other areas of specialty/work

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Person responsible for updating data

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Position

Gynecologist and obstetrician

Other areas of specialty/work

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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