

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparison between the effect of Isoniazid together with Misoprostol and Misoprostol on abortion in the first three months of pregnancy.

Protocol summary

Study aim

Comparison of the efficacy of vaginal isoniazid with sublingual misoprostol and sublingual misoprostol alone in inducing abortion during the first three months of pregnancy

Design

A randomized controlled clinical trial with parallel groups, without blinding

Settings and conduct

In the first group vaginal isoniazid (mg 1500) is placed and 12 hours later sub-lingual misoprostol (800 µg) administered. In the absence of vaginal bleeding or pain, repeat up to 3 doses every 3 hours. In second Group, they receive only the second vaginal misoprostol. After the first dose of misoprostol, abortion was considered successful within 24 hours after ablation, and vaginal ultrasound will be performed to check for residuals. In the absence of residuals, "complete abortion" is reported. In cases of residues below 3 cm, "successful disposal" and "incomplete abortion" are reported. Misoprostol 800µg should be used again every three hours for up to three doses if residuals above 3 cm, failure to excretion, or visualization of pregnancy sacs. At the end of the second 24 hours, vaginal ultrasound was performed to examine the remains. Patients were divided into one of the following groups based on the interval between the onset of misoprostol and the expulsion of the tissue that is considered as successful treatment: Abortion under 6 hours Abortion under 12 hours Abortion under 24 hours Abortion under 48 hours

Participants/Inclusion and exclusion criteria

All Grade One pregnant women with no vaginal bleeding and whole package with gestational age less than or equal to 91 days based on LMP and ultrasound (blighted ovum, missed abortion, legal abortion) and are candidates for termination of pregnancy or have a forensic abortion permit are enrolled in the study.

Intervention groups

The intervention group received isoniazid plus

misoprostol The control group received only misoprostol.

Main outcome variables

abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190819044561N1**

Registration date: **2020-02-19, 1398/11/30**

Registration timing: **retrospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **1**

Registration date

2020-02-19, 1398/11/30

Registrant information

Name

Mahshid Shirvani Ghadikolaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7762 6006

Email address

shirvani.mahshid777@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

2018-04-21, 1397/02/01

Actual recruitment end date

2019-09-21, 1398/06/30
Trial completion date
 2019-09-21, 1398/06/30

Scientific title
 A comparison between the effect of Isoniazid together with Misoprostol and Misoprostol on abortion in the first three months of pregnancy.

Public title
 A comparison between the effect of Isoniazid together with Misoprostol and Misoprostol on abortion in the first three months of pregnancy.

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Gestational age less than 13 weeks Primigravida Without vaginal bleeding Closed cervical os Candidate for pregnancy termination
Exclusion criteria:

Age
 No age limit

Gender
 Female

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: **80**
 Actual sample size reached: **80**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Blocked randomization

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-04-16, 1397/01/27

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9511290012

Health conditions studied

1

Description of health condition studied

Abortion

ICD-10 code

O03

ICD-10 code description

Miscarriage

Primary outcomes

1

Description

Abortion Time

Timepoint

During the intervention

Method of measurement

hour

Secondary outcomes

1

Description

Vomit

Timepoint

During the intervention

Method of measurement

See

2

Description

Diarrhea

Timepoint

During the intervention

Method of measurement

see

3

Description

Fever

Timepoint

During the intervention

Method of measurement

Celsius

Intervention groups

1

Description

Intervention group: First, 1500 mg of vaginal isoniazid is administered, and then 12 hours later, 800 micrograms of sub-lingual misoprostol. Repeat every three hours to three doses.

Category

Treatment - Drugs

2

Description

Control group: Only 800 µg of sublingual misoprostol was given every 3 hours up to 3 doses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbarabadi Hospital

Full name of responsible person

Mahshid Shirvani Ghadikolaie

Street address

Akbarabadi Hospital, Ferdows Garden Station,
Mowlavi Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 5560 6034

Email

akbarabadihosp@yahoo.com

2

Recruitment center

Name of recruitment center

Rasul Akram Hospital

Full name of responsible person

Mahshid Shirvani Ghadikolaie

Street address

Nayayesh St., Sattarkhan St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 6435 1021

Email

admsite@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Abbas Motevalian

Street address

Iran University of Medical Sciences, Shahid Hemmat
Highway, Tehran, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

motevalian.a@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Mahshid Shirvani Ghadikolaie

Position

Obstetrics and Gynecology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Rasoul Akram Hospital, Nayayesh St, Sattarkhan St,
Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

0098 21 64351

Email

shirvani.mahshid777@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahshid Shirvani Ghadikolaei

Position

Obstetrics and Gynecology Resident

Latest degree

Medical doctor

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City

Tehran

Province

Tehran

Postal code

1449614535

Phone

0098 21 64351

Email

shirvani.mahshid777@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mahshid Shirvani Ghadikolaei

Position

Obstetrics and Gynecology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Rasoul Akram Hospital, Niayesh Street, Sattarkhan Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

0098 21 64531

Email

shirvani.mahshid777@gmail.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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 12 months after publishing results

To whom data/document is available

Gynecologists

Under which criteria data/document could be used

Use of data and documentation is permitted by mentioning the source name.

From where data/document is obtainable

Dr Mahshid Shirvani shirvani.mahshid777@gmail.com

What processes are involved for a request to access data/document

After contacting Dr. Shirvani if your request complies with study policies, the data will be available to you.

Comments