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

0o3

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 Ghadikolaei
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 Ghadikolaei
Street address
Nayayesh St., Sattarkhan St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 6435 1021
Email
adminsite@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 Ghadikolaei
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

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 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