

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparative study of drug treatment outcomes (OCP and Methergine) in aborted patients with pregnancy remnants

Protocol summary

Study aim

Comparative study of drug treatment outcomes (OCP and Methergine) in aborted patients with pregnancy remnants

Design

This is a single-blinded randomized clinical trial with a parallel design. This study is randomized, phase 2-3 study will be performed on 80 patients with pregnancy debris. A random number table is used for randomization and participants are assigned to two intervention groups.

Settings and conduct

This study, which will be conducted at Al-Zahra Hospital in Isfahan, is a single-blinded one. In this single-blinded study, participants will be kept blind to the type of drug. Before starting the study, patients are treated with Misoprostol according to the protocol. They enter the study 10 days after receiving Misoprostol according to the inclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 18 years; Forgotten abortion under 20 weeks; Hemoglobin above 10; No contraindications to receiving Methergine or OCP; Stability of the patient's vital signs at the beginning of the treatment
Exclusion criteria: Active liver disease; Cardiovascular disease; HTN infection; Severe bleeding

Intervention groups

The first intervention group will receive OCP (0.03 mg Ethinylestradiol and 0.15 Desogestrel) daily for 21 days. The second intervention group, patients will receive three times a day (0.25 mg oral Methergine) for 10 days. In addition, in both groups 100 mg oral Doxycycline capsules, every 12 hours for 10 days will be administered.

Main outcome variables

Incidence of infection; Gastrointestinal symptoms, cardiovascular complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220430054708N1**

Registration date: **2022-05-31, 1401/03/10**

Registration timing: **prospective**

Last update: **2022-05-31, 1401/03/10**

Update count: **0**

Registration date

2022-05-31, 1401/03/10

Registrant information

Name

Samira Rafiee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3337 0835

Email address

samira.rafaee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-14, 1401/03/24

Expected recruitment end date

2022-12-15, 1401/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of drug treatment outcomes (OCP and Methergine) in aborted patients with pregnancy remnants		Ethics committee of Isfahan University of Medical Sciences	
Public title		Street address	
study of the effect of drug treatment (OCP and Methergine) in patients with pregnancy remnants		Isfahan University of Medical Sciences, Hezar Jarib St..	
Purpose		City	
Treatment		Isfahan	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		Kermanshah	
Age over 18 years Forgotten abortion under 20 weeks Hemoglobin above 10 No contraindications to receiving Methergine or OCP Stability of the patient's vital signs at the beginning of the treatment		Postal code	
Exclusion criteria:		8174673461	
Active liver disease Cardiovascular disease HTN infection Advanced neurological disease Symptoms of infection Severe bleeding		Approval date	
Age		2022-03-04, 1400/12/13	
From 18 years old		Ethics committee reference number	
Gender		IR.MUI.MED.REC.1400.825	
Female		Health conditions studied	
Phase		<u>1</u>	
2-3		Description of health condition studied	
Groups that have been masked		Placental remnants	
Participant		ICD-10 code	
Sample size		O03.4	
Target sample size: 80		ICD-10 code description	
Randomization (investigator's opinion)		Incomplete spontaneous abortion without complication	
Randomized		Primary outcomes	
Randomization description		<u>1</u>	
Simple random method. 80 cards are selected and numbers from 1-80 are inserted on the cards. The cards are placed in an envelope. Two of the design partners take one card out of the envelope each time and announce the card number. Paired numbers are assigned to the intervention group and odd numbers to the control group		Description	
Blinding (investigator's opinion)		Incidence of infection	
Single blinded		Timepoint	
Blinding description		At the beginning of the study and one month after the start of the study	
Participants will consciously participate in the study but OCP and methergine will label as A and B. Participants will not know whether the drug is A or B.		Method of measurement	
Placebo		Based on the clinical signs, the fever is mostly equal to 38 degrees Celsius	
Not used		<u>2</u>	
Assignment		Description	
Parallel		Gastrointestinal symptoms	
Other design features		Timepoint	
Secondary Ids		At the beginning of the study and one month after the start of the study	
empty		Method of measurement	
Ethics committees		visual analogue scale	
<u>1</u>		<u>3</u>	
Ethics committee		Description	
Name of ethics committee		Cardiovascular complications	
		Timepoint	
		At the beginning of the study and one month after the start of the study	
		Method of measurement	
		Clinical signs	
		Secondary outcomes	
		empty	

Intervention groups

1

Description

The first intervention group will receive OCP (0.03 mg Ethinylestradiol and 0.15 Desogestrel) daily for 21 days. In addition, 100 mg oral Doxycycline capsules every 12 hours for 10 days will be administered.

Category

Treatment - Drugs

2

Description

The second intervention group, patients will receive three times a day (0.25 mg oral Methergine) for 10 days. In addition, 100 mg oral Doxycycline capsules every 12 hours for 10 days will be administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Samira Rafiei

Street address

Al-Zahra Educational and Medical Center, Safa Boulevard,

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

samira.rafaee@ymail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shahin Sheyrani

Street address

Vice Chancellor for Research and Technology, Building No. 4, Isfahan University of Medical Sciences, Hezar Jerib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

research@mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Samira Rafiei

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Isfahan University of Medical Sciences, Hezar Jarib St..

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

samira.rafaee@ymail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Elham Naghshineh

Position

Faculty member of Isfahan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Isfahan University of Medical Sciences, Hezar Jarib St..

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

Naghshineh@yahoo.com

Street address

Isfahan University of Medical Sciences, Hezar Jarib St..

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

samira.rafaee@ymail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Person responsible for updating data**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Samira Rafiei

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics