Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 groupe100 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.rafiee@ymail.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

Public title
study of the effect of drug treatment (OCP and Methergine) in patients with pregnancy remnants
Purpose
Treatment
Inclusion/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 Advanced neurological disease Symptoms of infection Severe bleeding
Age
From **18 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Blinding (investigator's opinion)
Single blinded
Blinding description
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.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib St..
City
Isfahan
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Kermanshah
Postal code
8174673461
Approval date
2022-03-04, 1400/12/13
Ethics committee reference number
IR.MUI.MED.REC.1400.825

Health conditions studied

1

Description of health condition studied
Placental remnants
ICD-10 code
O03.4
ICD-10 code description
Incomplete spontaneous abortion without complication

Primary outcomes

1

Description
Incidence of infection
Timepoint
At the beginning of the study and one month after the start of the study
Method of measurement
Based on the clinical signs, the fever is mostly equal to 38 degrees Celsius

2

Description
Gastrointestinal symptoms
Timepoint
At the beginning of the study and one month after the start of the study
Method of measurement
visual analogue scale

3

Description
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Samira Rafiei
Position
Resident of Obstetrics and Gynecology
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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