Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of the efficacy and side effects of oxytocin + misoprostol with methyl ergonovine (metergin) + misoprostol and misoprostol alone in the excretion of pregnancy products.

Protocol summary

Study aim

Effectiveness and Side Effects of Oxytocin + Misoprostol with Methyl Ergovin (Miginal) + Misoprostol and Misoprostol alone in disposal of of pregnancy products

Design

Clinical trial with control group and parallel groups. blinded and randomised number of patients:90

Settings and conduct

After entering the study, patients were randomly divided into three groups. The first group was the control group and only misoprostol was administered. The second and third groups were treated as case groups with different regimes .in the second group misoprostol and oxytocin and in third group Misoprostol and metergine were administered respectively as a medicinal regimens for 3 days. After that ultrasound was performed to check the residual tissue. If the remaining tissue is re-observed in ultrasonography, the mentioned above drugs were repeated for 3 days. If the remaining tissue was repeated again we continued the mentioned drugs 3 days more, and if the remaining tissue was observed again, the patient will undergo surgery. This study was conducted at Jahrom University of Medical Sciences .Participants and Health and medical staff were kept blind from the beginning to the end of the study

Participants/Inclusion and exclusion criteria

inclusion criteria: Willingness to outpatient treatment to dispose of pregnancy products gestational age less than 14 weeks no history of any high risk disease exclusion criteria: Intolerance to drug treatment Fatigue from the treatment process and unwillingness to continue the study

Intervention groups

Patients were randomly divided into three groups. The first group was the control group and they were given only misoprostol. The second and third groups were treated with different regimens. The second group received misoprostol and oxytocin and the third group received misoprostol and metergin as medication.

Main outcome variables

time of disposal of pregnancy products

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200122046221N1**
Registration date: **2020-05-11, 1399/02/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-11, 1399/02/22**
Update count: **0**

Registration date

2020-05-11, 1399/02/22

Registrant information

Name

athar rasekhjahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5426 6602

Email address

drrasekh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-02, 1399/01/14

Expected recruitment end date

2020-12-23, 1399/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy and side effects of oxytocin + misoprostol with methyl ergonovine (metergin) + misoprostol and misoprostol alone in the excretion of pregnancy products.

Public title

The efficacy and side effects of oxytocin, methyl ergonovine (metergin) and misoprostol in the excretion of pregnancy products.

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

tendency toward outpatient treatment gestational age less than 14 week not presence of high risk disease

Exclusion criteria:

presence of a major disease the patients who can not tolerate drugs those who get tired from the process of treatment

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization method will be used, the randomization unit will be individualized and we will use random number table method to generate random sequence.People are divided into three groups (two case and one control group) . They also pack medication based on codes and another person who is unaware of the randomization process gives the drugs to the patients according to the mentioned codes .This randomization and allocation will be remained hidden from researchers and participants until the statistical analysis is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

despite obtaining written consent from patients to participate in the study, they only knew that they would participate in the study to find the best way to get rid of pregnancy products after first trimester abortion, but they did not know which group of drugs was included in the drug coding (one-way blinding).the ampoules and tablets were presented to the researchers in similar syringes and covers respectively (with special codes) so that it could not be identified for the researchers. Accordingly, the researchers who assisted patients in prescribing the drug, although they knew what the drug's content was in each package, were unaware of the research hypotheses, so they did not know which intervention group and which control group to use , It should be noted that the participants in each group were unaware of the drug regime of the opposite group.(double-blinding). And because the drugs were prescribed to patients with a coding system, the researcher did not know when the data was analyzed until the final calculations were performed. Because the researcher knew about the coding system and the researchers did not know about this system, but the data reached the researcher with numbers 1, 2 and 3, so the researcher did not know until the end of the analysis and before generalizing the calculations to the groups that the numbers one and Two or three belong to which codes A, B and C. It is obvious that the researcher's help wrote down the numbers belonging to the codes somewhere and gave them to the researcher after analyzing the data. In this research, three-way blinding technique was found. Coding system: control group: a, second group: b, third group: c (when delivering drug envelopes coded by the researcher with the help of the researcher) Group naming system with numbers: control group: 1, second group: 2, third group: 3 (when delivering data on therapeutic effects and side effects by the researcher to the researcher) Note: Research Assistant for Researcher after Data Analysis: Control Group: A-1, Second Group: B-2, Third Group C-3.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

jahrom university of medical science ethic comitte

Street address

jahrom,motahari street,jahrom university of medical science

City

jahrom

Province

Fars

Postal code

۷۴۱۴۸-۴۶۱۹۹

Approval date

2017-06-03, 1396/03/13

Ethics committee reference number

IR.JUMS.REC.1396.143

Health conditions studied

1

Description of health condition studied
incomplete abortion in first trimester
ICD-10 code
O03.4
ICD-10 code description
Incomplete spontaneous abortion without complication

Primary outcomes

1

Description
Time of disposal of pregnancy products
Timepoint
Before starting the study . 3-6-9 days after starting the drug regimen
Method of measurement
The time from partial abortion to complete disposal of pregnancy products was measured

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: How to prescribe the drugs in the first intervention group: Oxytocin 1 amp (dose of amp: 10 unit) in the morning, 1 amp in the afternoon and 1 amp in the evening(IM injection) + misoprostol at a dose of 200 mg every 6 hours up to 3 days.An ultrasound is then performed to examine the remaining tissue And if the products are not passed, this diet will be repeated for another two periods.
Category
Diagnosis

2

Description
Intervention group: How to administer the drugs in the second intervention group:1 amp metergin every 8 hour IM and tab misoprostol at a dose of 200 mg every 6 hours up to 3 days.An ultrasound is then performed to examine the remaining tissue And if the products are not passed, this diet will be repeated for another two periods.
Category
Diagnosis

3

Description
Control group: This group will only receive Misoprostol 200mg sublingual tablets every 6 hours up to 3 days.An ultrasound is then performed to examine the remaining tissue And if the products are not passed, this diet will be repeated for another two periods
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
jahrom university of medical sciences
Full name of responsible person
jahrom university of medical sciences
Street address
ProMotahhari St.- After School of Nursing- Jahrom University of Medical Sciences- Pardis Site
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Phone
+98 71 5433 1521
Email
Pazhuheshi@jums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
athar rasekhjahromi
Street address
Jahrom-Ostad Motahari Street-After School of Nursing-Jahrom University of Medical Sciences-Pardis site.
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Phone
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Email
drrasekh@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jahrom 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

Jahrom University of Medical Sciences

Full name of responsible person

athar rasekhjahromi

Position

medical doctor(gynecologist)

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Jahrom-Ostad Motahari Street-After School of Nursing-Jahrom University of Medical Sciences-Pardis site.

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Phone

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Email

drrasekh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

athar rasekhjahromi

Position

medical doctor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

athar rasekhjahromi

Position

medical doctor

Latest degree

Specialist

Other areas of specialty/work

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Title and more details about the data/document

data would be presented according to the jahrom university of medical sciences protocols

When the data will become available and for how long

according to the jahrom university of medical sciences protocols

To whom data/document is available

according to the jahrom university of medical sciences protocols

Under which criteria data/document could be used

according to the jahrom university of medical sciences protocols

From where data/document is obtainable

jahrom university of medical sciences

What processes are involved for a request to access

data/document

according to the jahrom university of medical sciences

protocols

Comments