

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

An Outpatient Treatment of comparative study on the efficacy and side effects of oxytocin + misoprostol with methyl ergonovin (metergin) + misoprostol and only misoprostol in the expulsion of first trimester intrauterine fetal dead

Protocol summary

Study aim

Determining the effects of misoprostol alone, oxytocin + misoprostol and methylergonovine (Methergine) + misoprostol on the Excretion of pregnancy products after spontaneous fetal abortion

Design

An Outpatient Therapy Comparison of the Effectiveness and Side Effects of Oxytocin + Misoprostol with Methylergonovine (Methergine)+Misoprostol and Misoprostol alone in the excretion of pregnancy products in patients with fetal death in the first trimester of pregnancy

Settings and conduct

The first group is the control group and only Misoprostol is prescribed for them. Second and third groups will be treated as case or intervention groups with different regimens, which in the second group, Misoprostol and Oxytocin medications, and in the third group, Misoprostol and Methergine medications will be used as a drug regimen. Jahrom Motahari Hospital

Participants/Inclusion and exclusion criteria

□ The gestational age should be under 14 weeks. □ patients should not have a history of high-risk diseases (diabetes and hypertension, and hematologic disorders and cardiovascular diseases, etc.) □ patients should not have willing to undergo outpatient treatment for the excretion of pregnancy products. □ exclusion criteria: □ In the case of certain diseases, fever and hypertension patients are excluded from the study □ Also, patients who do not tolerate medications or get tired of the treatment

Intervention groups

The first group is the control group and only Misoprostol is prescribed for them. Second and third groups will be treated as case or intervention groups with different regimens, which in the second group, Misoprostol and

Oxytocin, and in the third group, misoprostol and methergine will be used as the drug regimen.

Main outcome variables

Frequency of success; The remaining tissue size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150407021653N19**

Registration date: **2019-10-04, 1398/07/12**

Registration timing: **retrospective**

Last update: **2019-10-04, 1398/07/12**

Update count: **0**

Registration date

2019-10-04, 1398/07/12

Registrant information

Name

Athar Rasekh Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 5432 6602

Email address

a.rasekh@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-26, 1397/07/04

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An Outpatient Treatment of comparative study on the efficacy and side effects of oxytocin + misoprostol with methyl ergonovin (metergin) + misoprostol and only misoprostol in the expulsion of first trimester intrauterine fetal dead

Public title

An Outpatient Treatment of comparative study on the efficacy and side effects of oxytocin + misoprostol with methyl ergonovin (metergin) + misoprostol and only misoprostol in the expulsion of first trimester intrauterine fetal dead

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who tend to undergo outpatient treatment for the excretion of pregnancy products. The gestational age should be under 14 weeks. Do not have a history of high-risk diseases (diabetes and blood pressure and blood problems and cardiovascular diseases, etc.).

Exclusion criteria:

If there are certain illnesses, fever and blood pressure will be excluded from the study. patients who do not tolerate drug therapy or will be tired of the treatment

Age

No age limit

Gender

Female

Phase

Bioequivalence

Groups that have been masked*No information***Sample size**Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **3****Randomization (investigator's opinion)**

Randomized

Randomization description

simple Randomization by random numbers table

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 Jahrom University of Medical Sciences

Street address

Motahari hospital, Motahari Street , Jahrom, Iran

City

Jahrom

Province

Fars

Postal code

۴۶۱۹۹-۷۴۱۴۸

Approval date

2018-02-26, 1396/12/07

Ethics committee reference number

IR.JUMS.REC.1396.143

Health conditions studied**1****Description of health condition studied**

Disposal of pregnancy products After spontaneous abortion

ICD-10 code

O03.4

ICD-10 code description

Incomplete spontaneous abortion without complication

Primary outcomes**1****Description**

Success in the pregnancy products excretion

Timepoint

During the 9 days after abortion

Method of measurement

Ultrasonography

2**Description**

The remaining tissue size

Timepoint

During the 9 days after abortion

Method of measurement

Ultrasonography

Secondary outcomes**1****Description**

Determine the mean time for disposal of pregnancy products after spontaneous abortion

Timepoint

After spontaneous abortion

Method of measurement

observation

Intervention groups

1

Description

Intervention group 1: Misoprostol and oxytocin medications are used as a drug regimen.

Category

Treatment - Drugs

2

Description

Intervention group 2: Misoprostol and Methergine medications are used as a drug regimen.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital

Full name of responsible person

Dr. Athar Rasekh Jahromi

Street address

Motahari Hospital , Motahari Street , Jahrom

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Dr. Athar Rasekh Jahromi

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Email

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Web page address

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

Dr. Athar Rasekh Jahromi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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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

No - There is not 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

Full data of unidentified people will be shared.

When the data will become available and for how long

1398-1399

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Data re-analysis can only be used in the new article if the name of the researchers is given.

From where data/document is obtainable

Calling to receive data through this email will be possible: Drrasekh@yahoo.com

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

After reviewing the objective, the request for data is provided to the person.

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

Jahrom University of Medical Sciences

Full name of responsible person

Dr. Athar Rasekh Jahromi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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